

EXHIBIT B



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(12) **United States Patent**
Tomes et al.

(10) **Patent No.:** **US 11,661,220 B2**(45) **Date of Patent:** ***May 30, 2023**

(54) **CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS**

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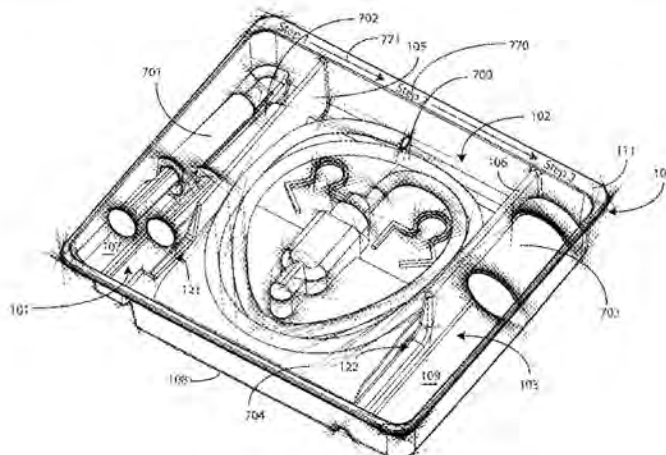
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(57)

ABSTRACT

A tray (100) for accommodating a coiled medical device, such as a catheter assembly (700), includes a first compartment (101), a second compartment (102), and a third compartment (103). The catheter assembly (700) and devices associated with a catheterization procedure, such as syringes (701, 702) containing sterile water and lubricating jelly and a specimen container (703) can be disposed within the tray. Printed instructions (1001) can be included with the tray

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US 11,661,220 B2

Page 2

(100). One or more layers of wrap material (2200) can be folded about the tray (100) to enclose the tray (100) and other items, such as an additional layer of wrap material (2701), packaged liquid hand sanitizer (2401), and packaged gloves (2402). When a health care services provider (3101) unfolds the wrap material, the same can be used to create a sterile field beneath a patient (3201).

22 Claims, 35 Drawing Sheets

Related U.S. Application Data

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 See application file for complete search history.

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Page 4

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US 11,661,220 B2

Page 5

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US 11,661,220 B2

Page 6

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US 11,661,220 B2

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US 11,661,220 B2

Page 8

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US 11,661,220 B2

Page 9

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US 11,661,220 B2

Page 10

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US 11,661,220 B2

Page 11

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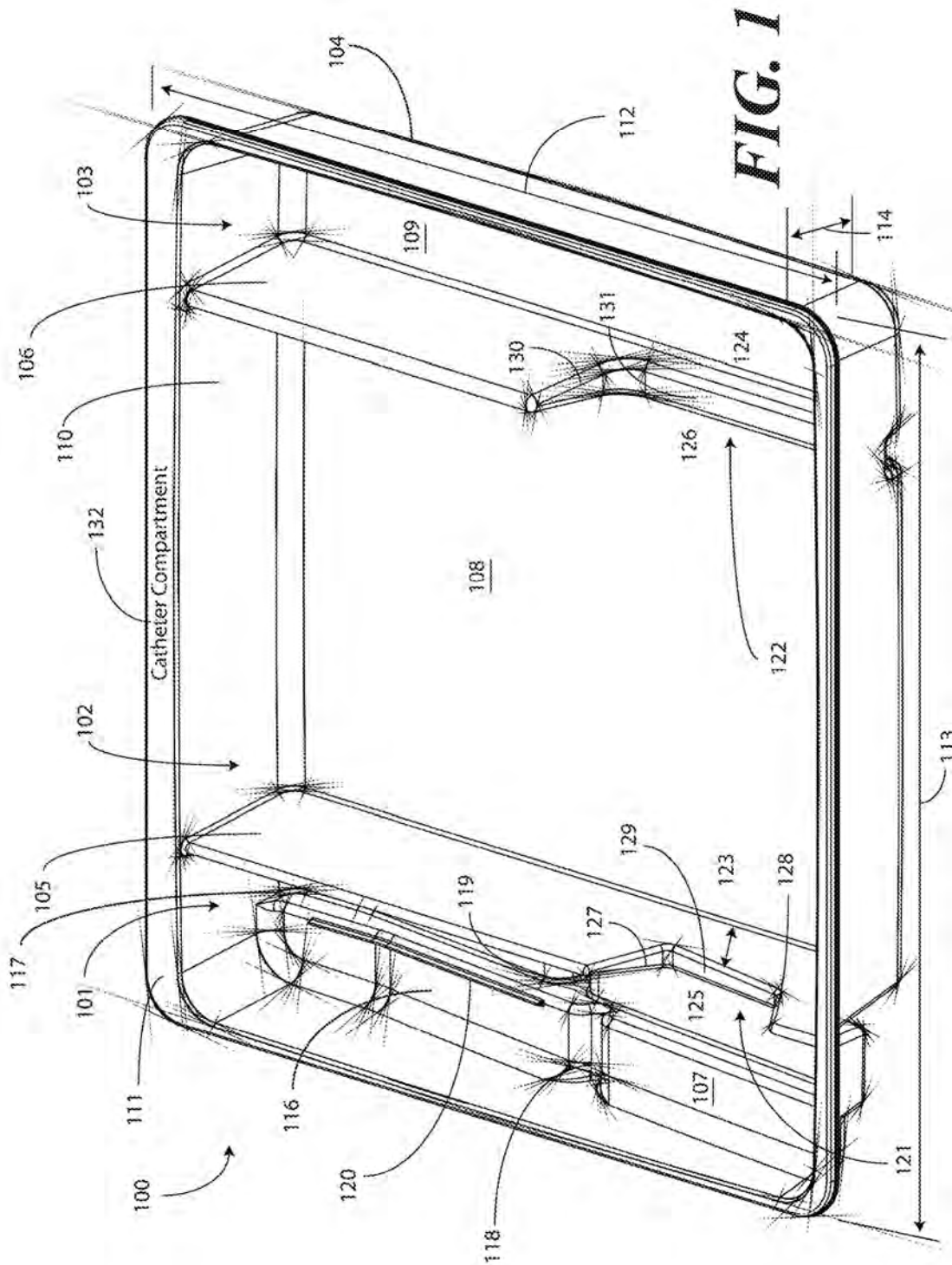
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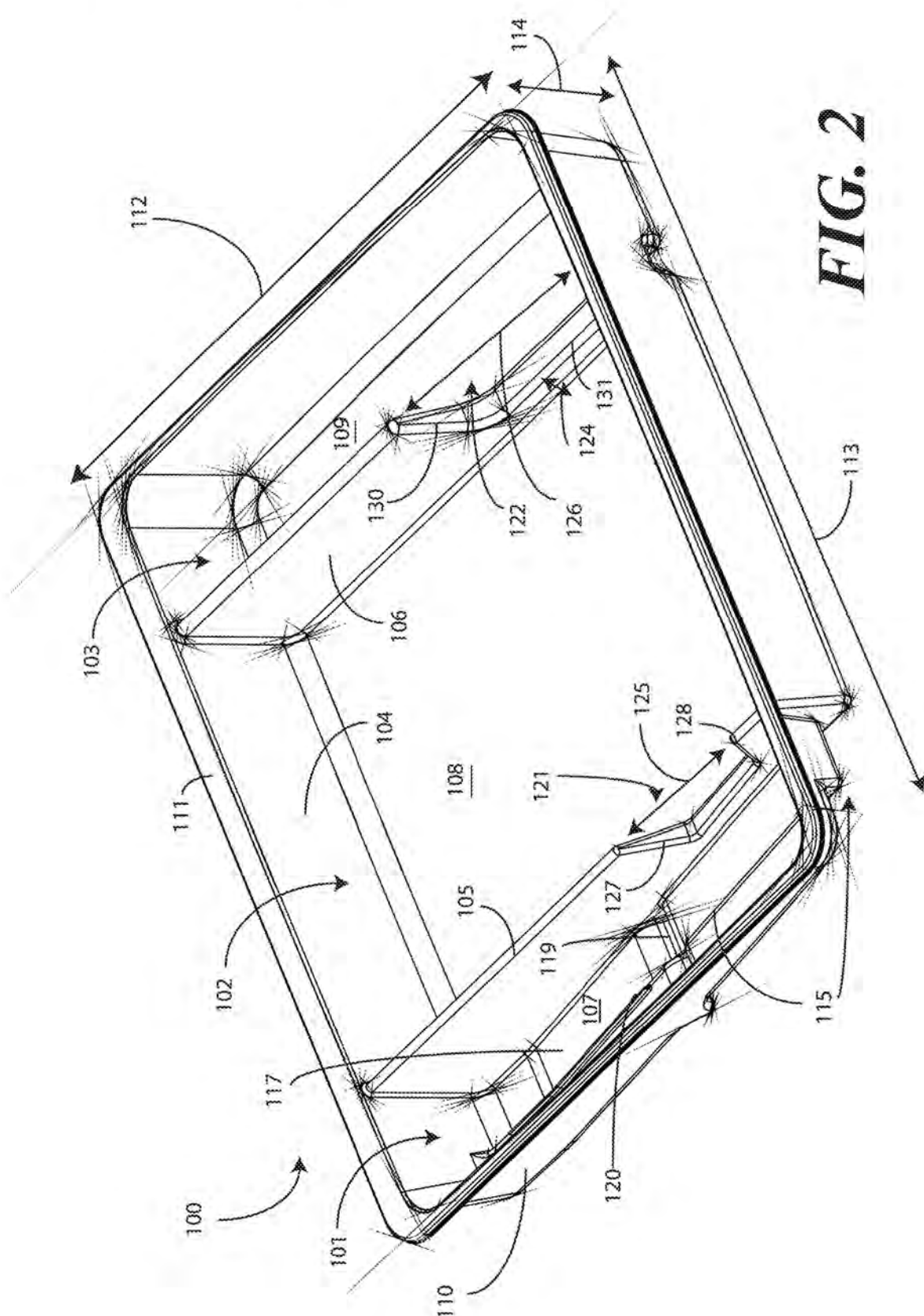
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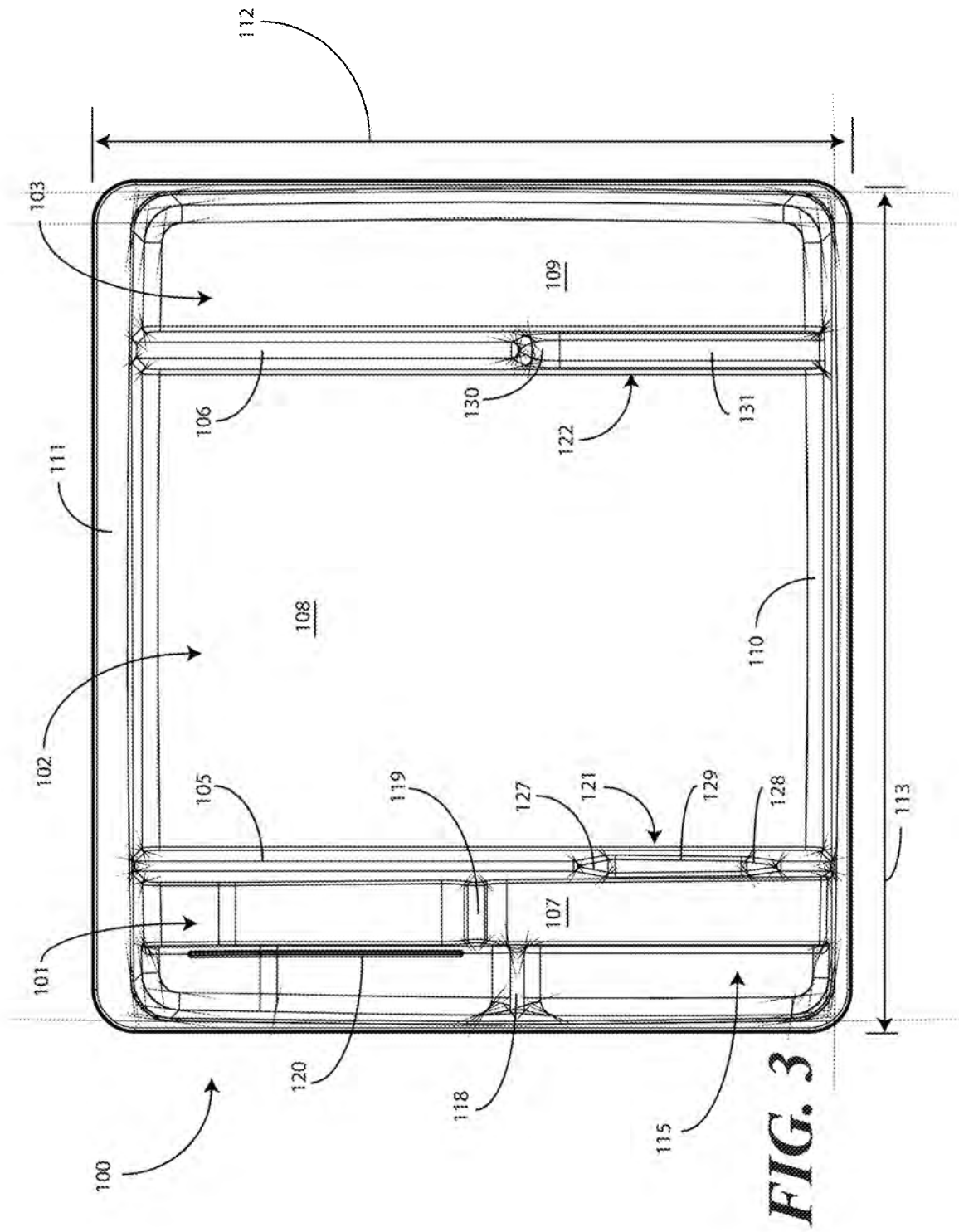
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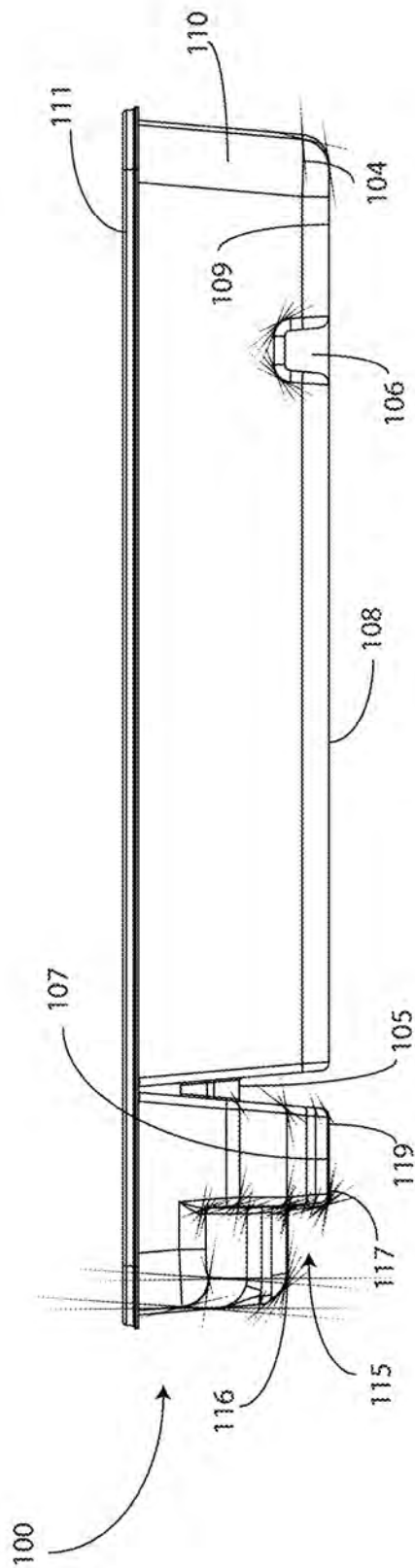


FIG. 4

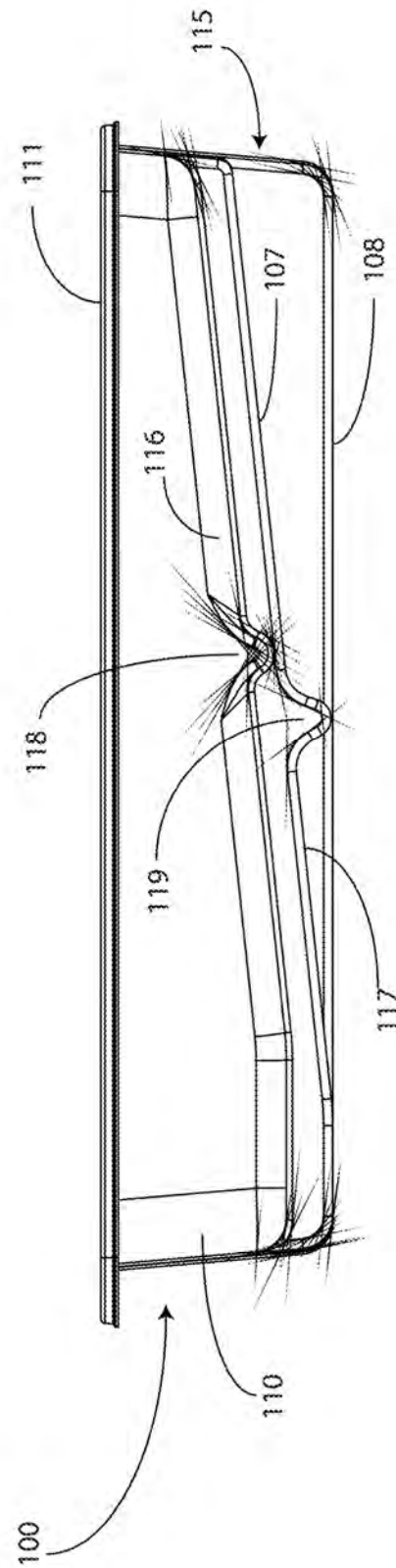
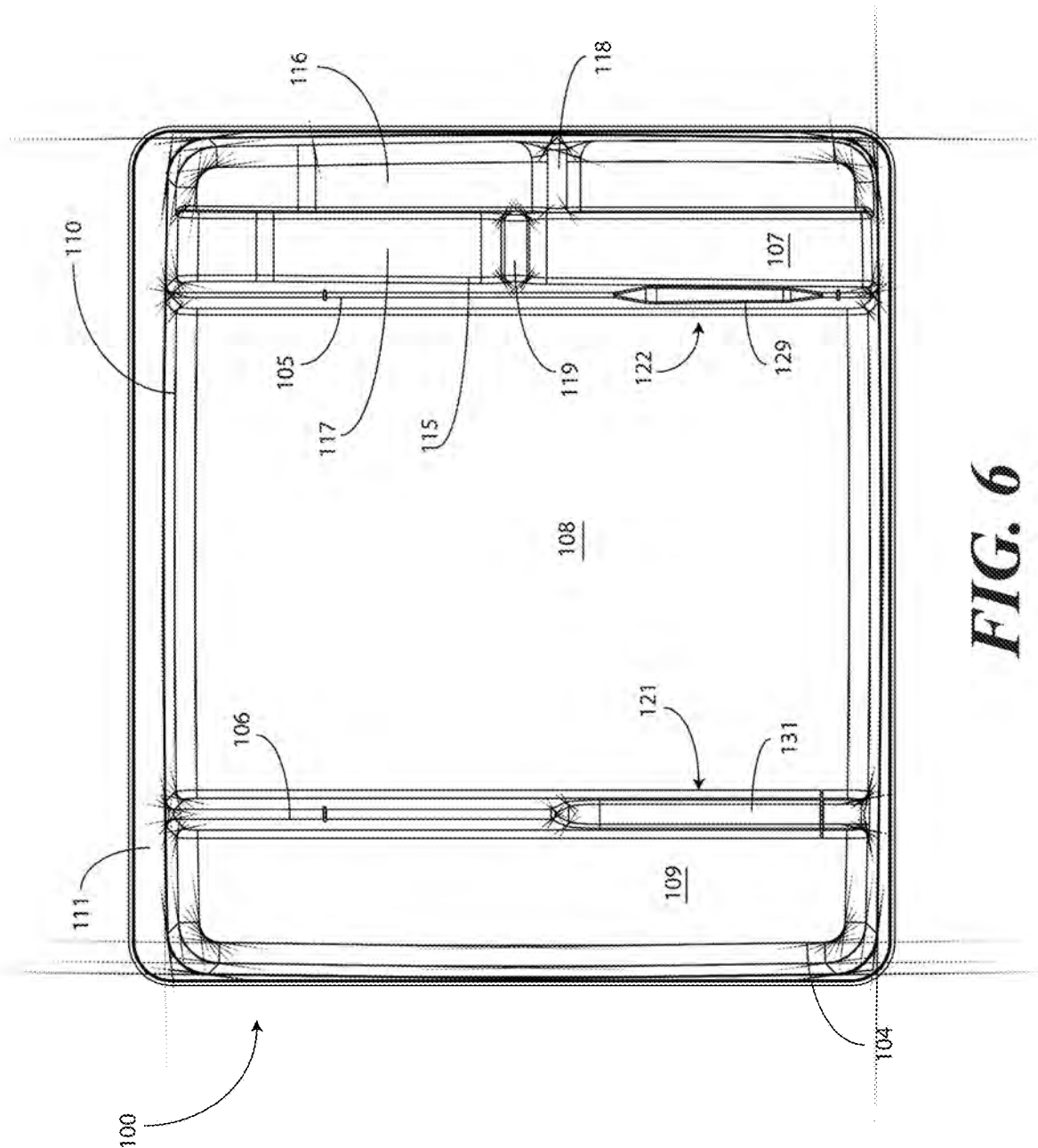


FIG. 5



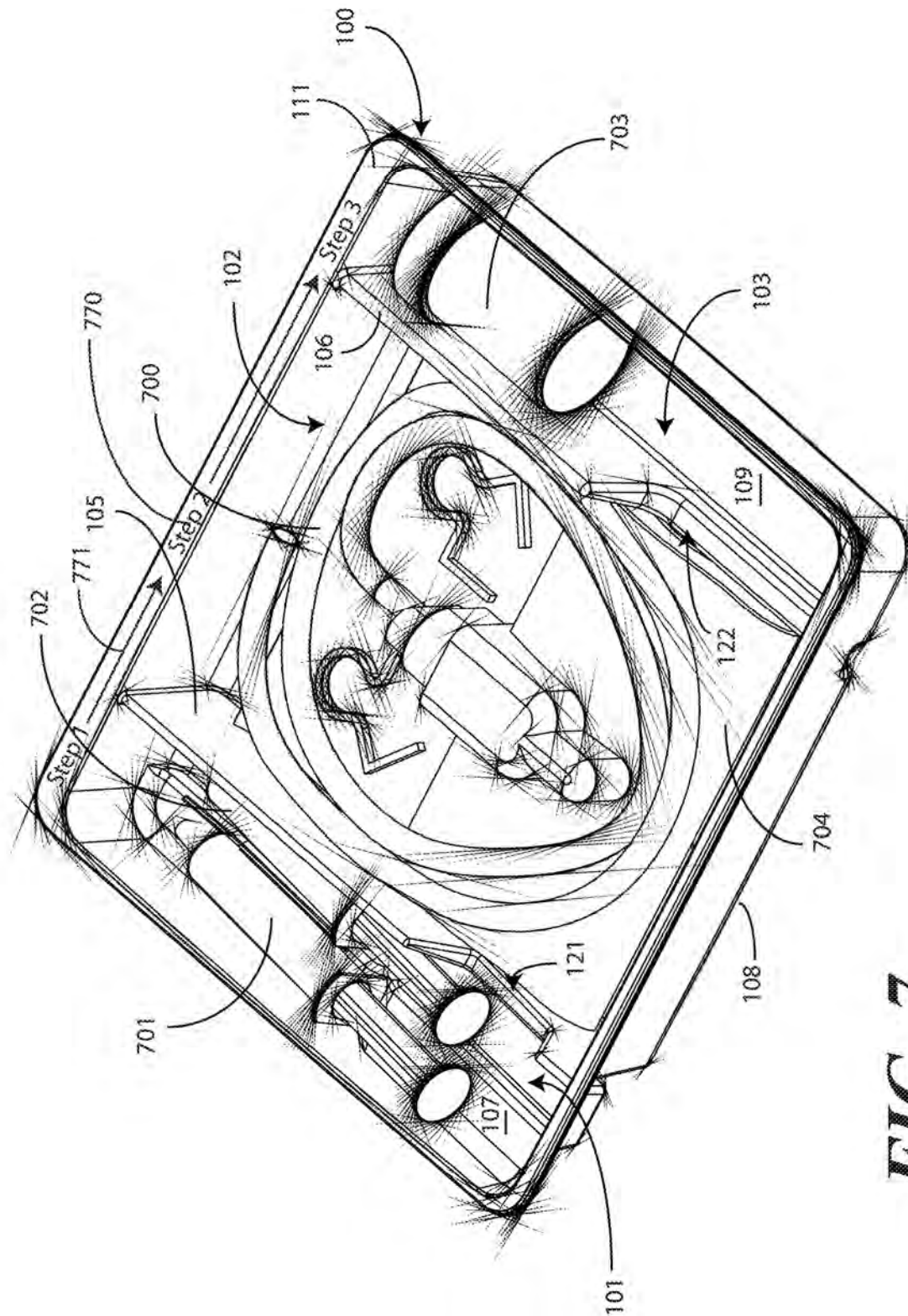
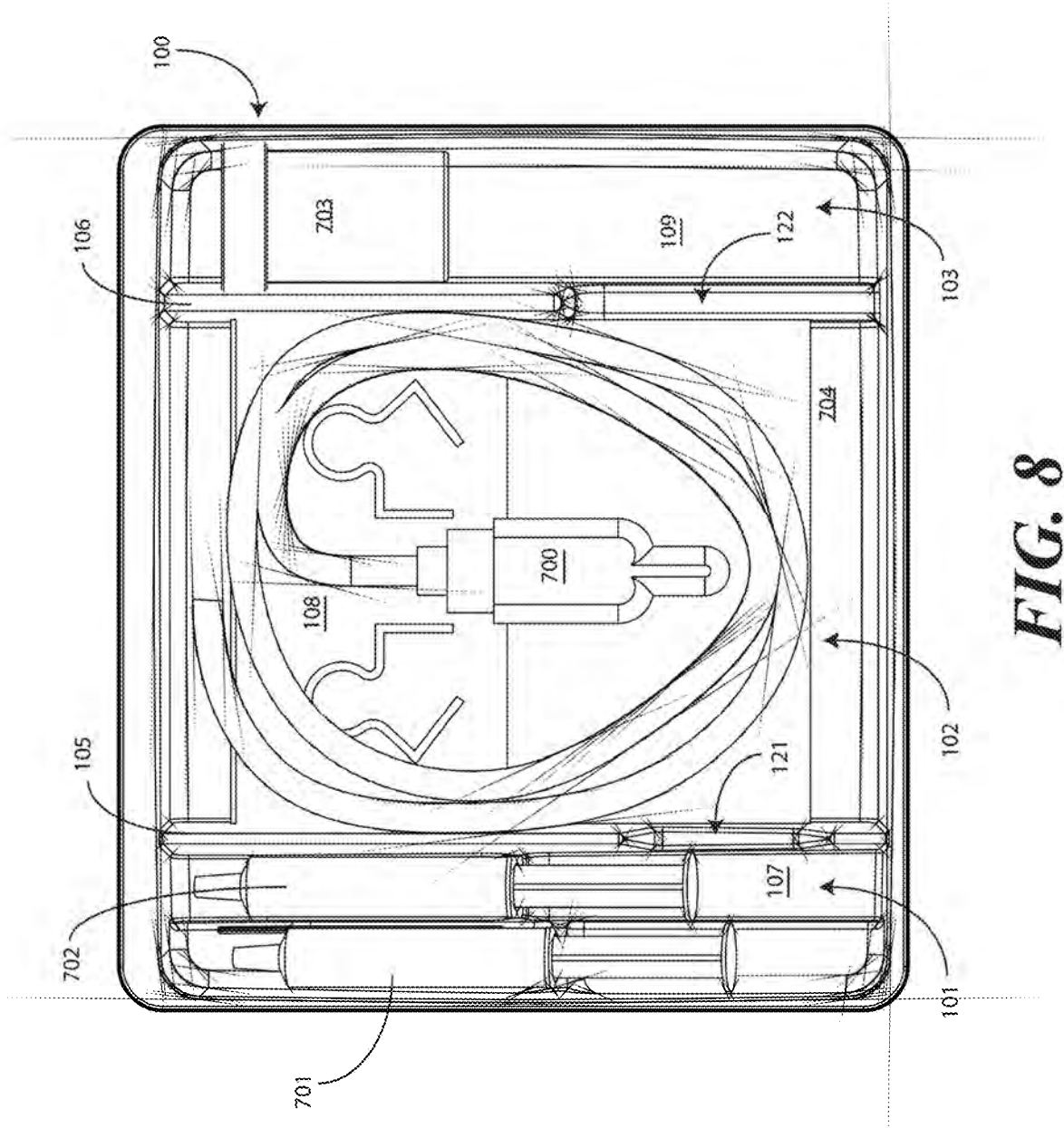


FIG. 7



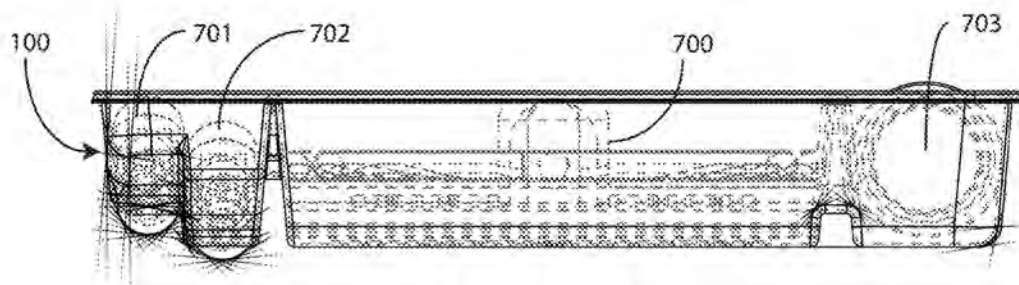


FIG. 9

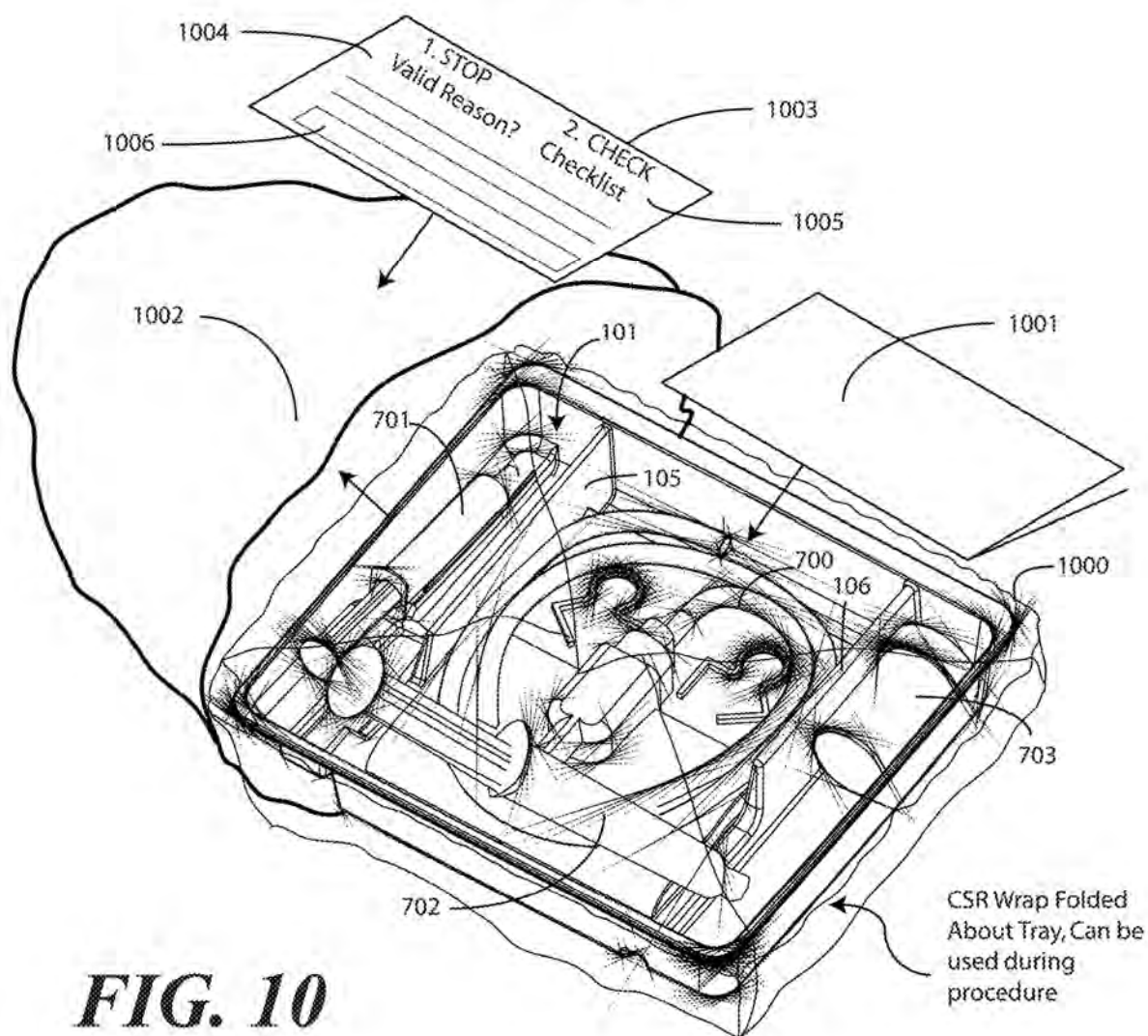


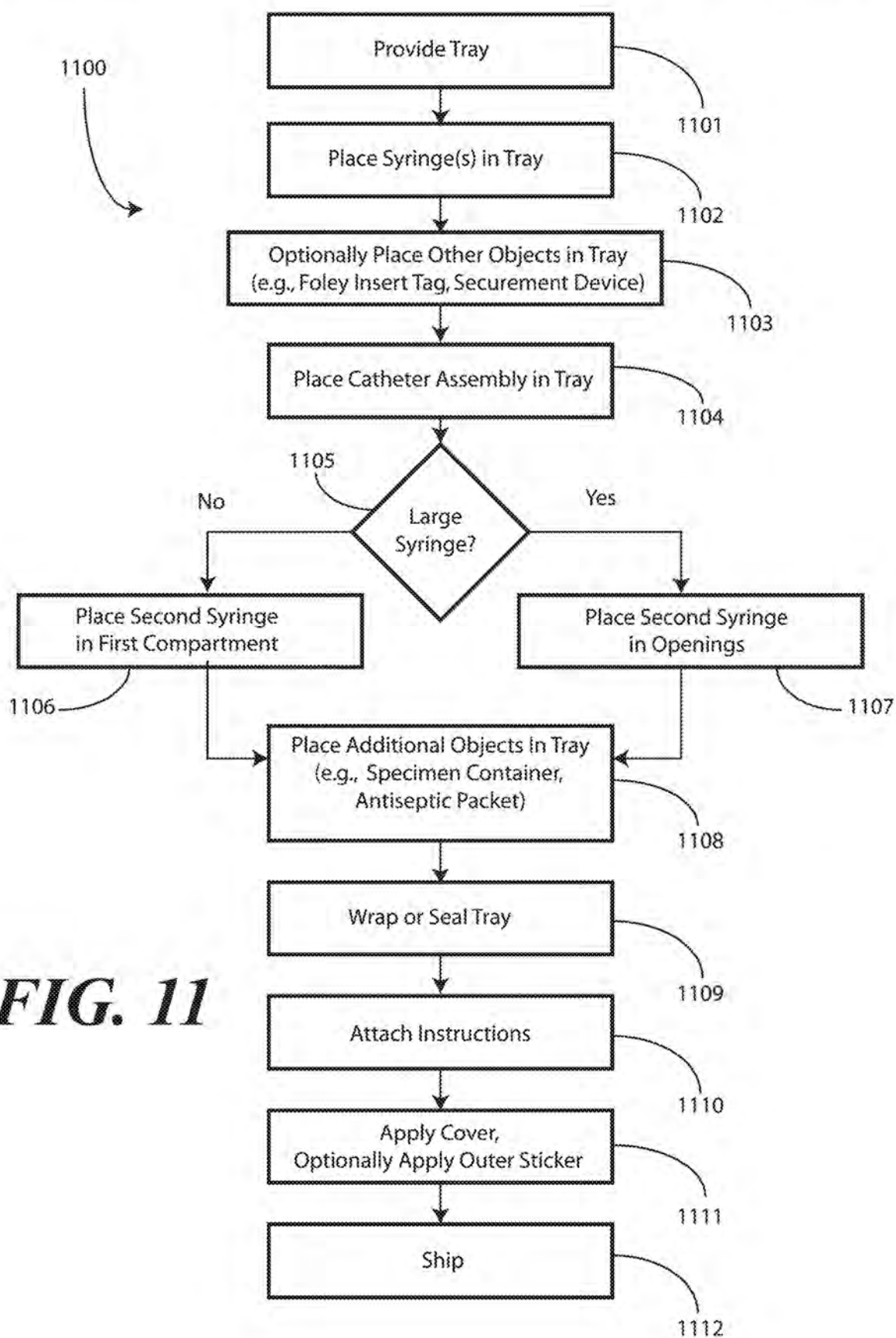
FIG. 10

U.S. Patent

May 30, 2023

Sheet 9 of 35

US 11,661,220 B2



U.S. Patent

May 30, 2023

Sheet 10 of 35

US 11,661,220 B2

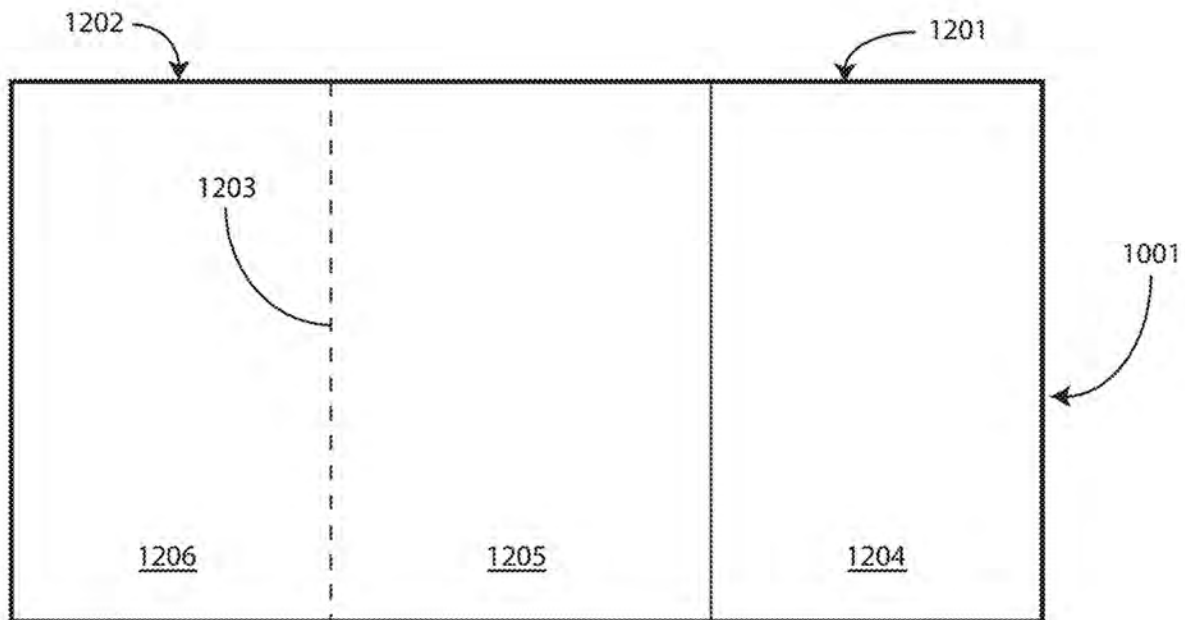


FIG. 12

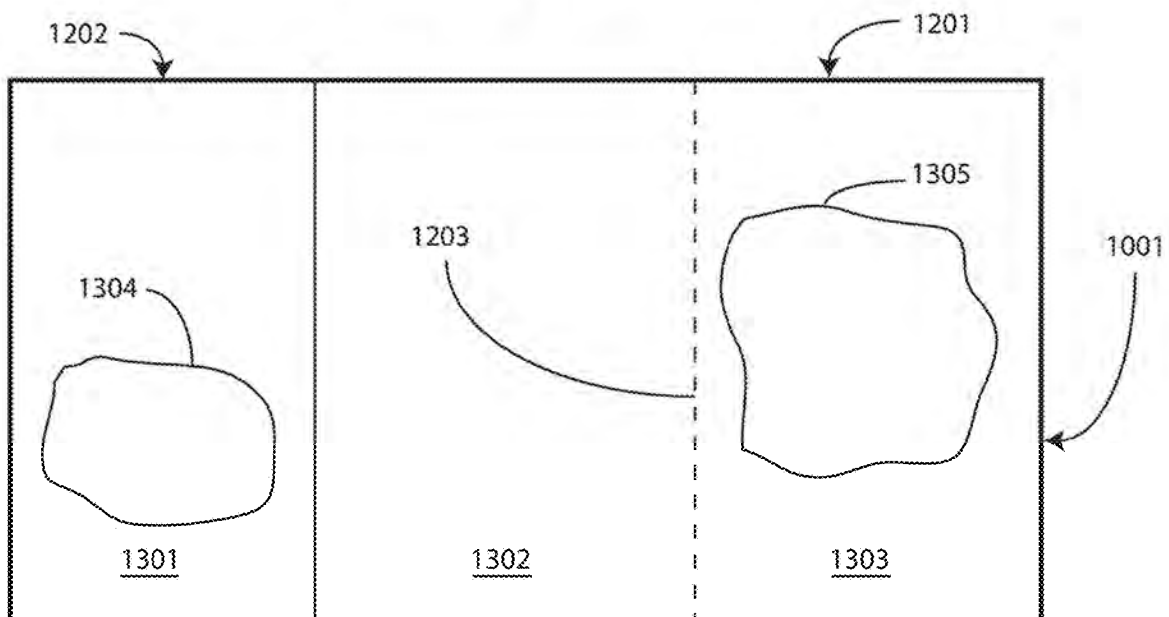
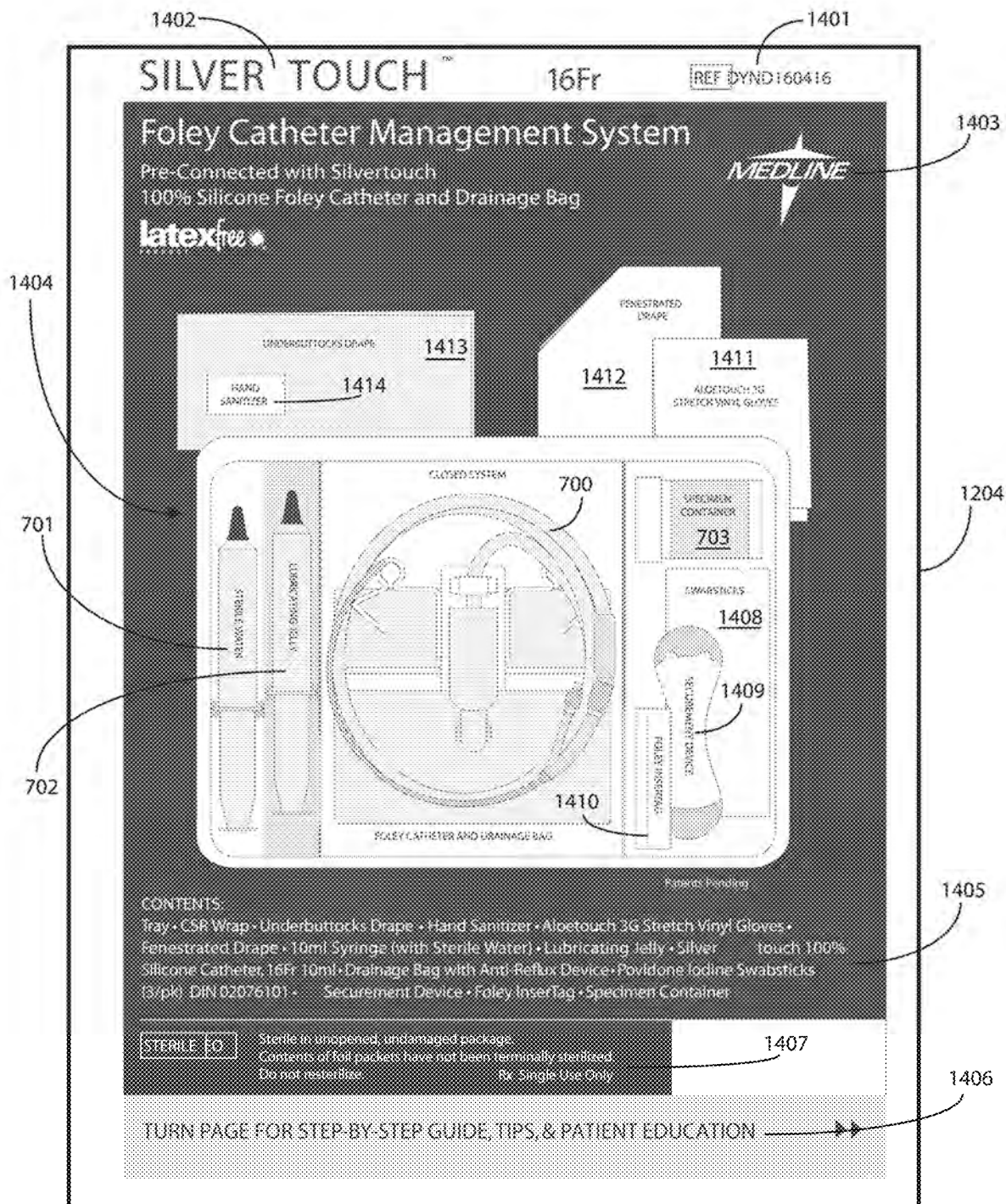
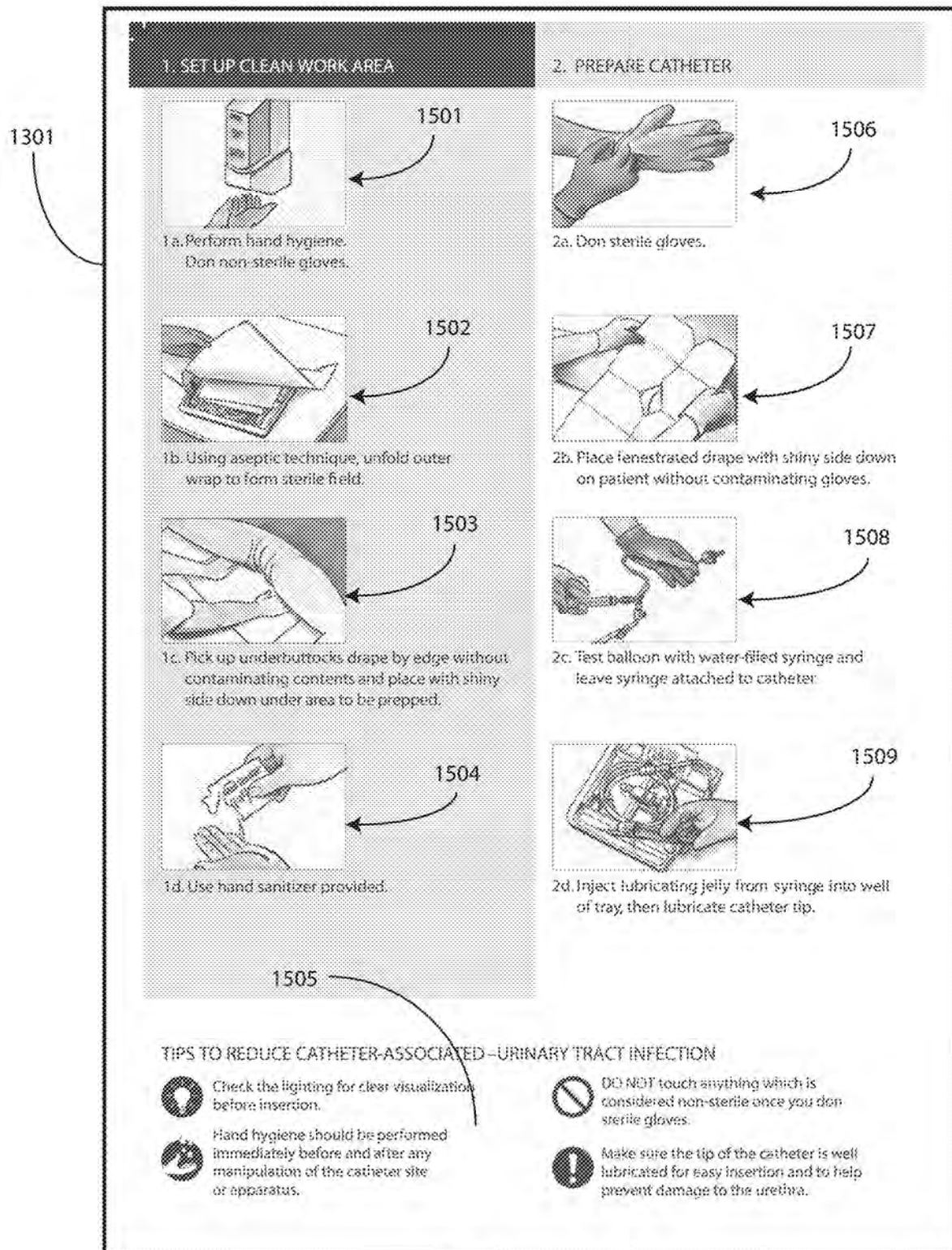
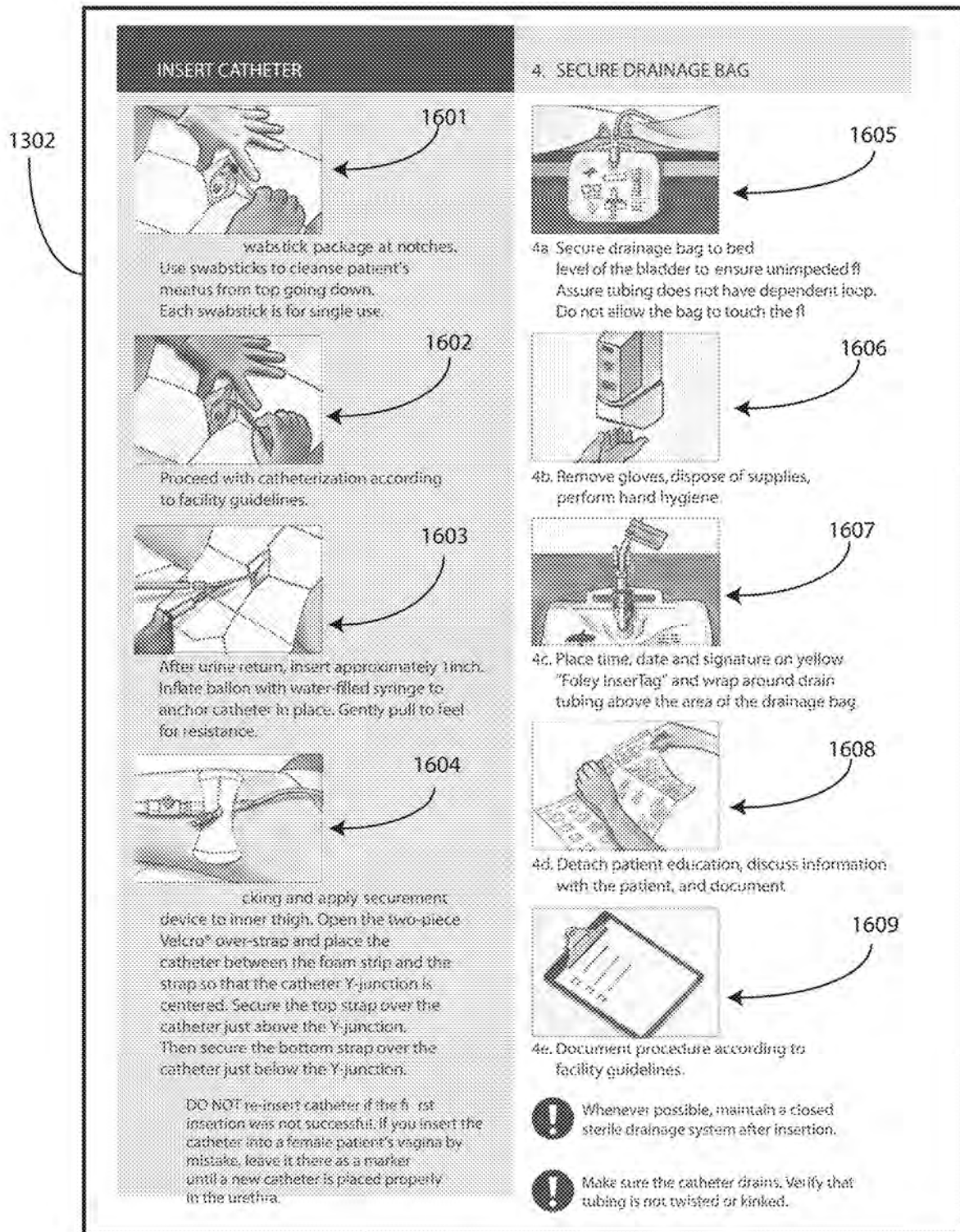
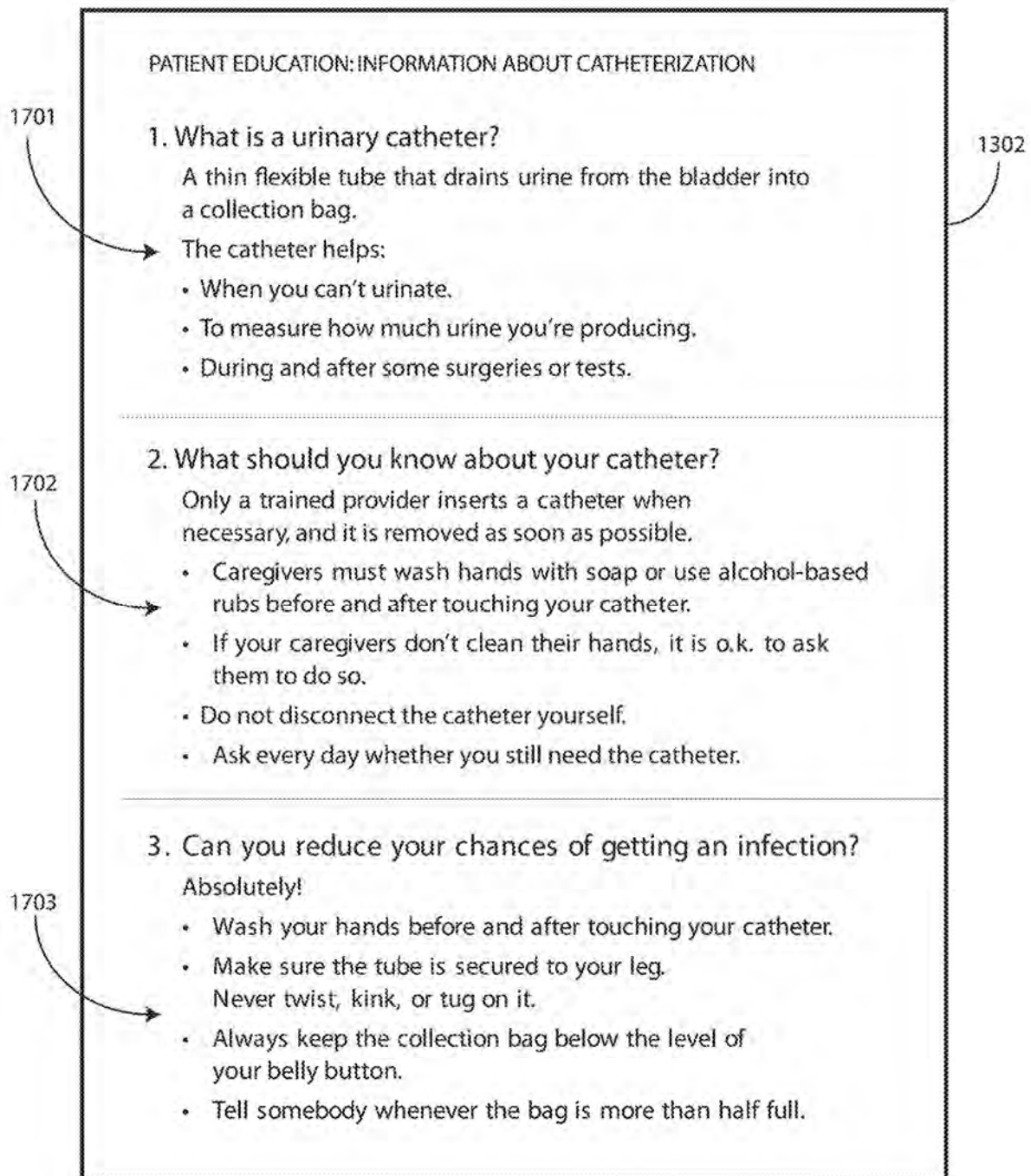


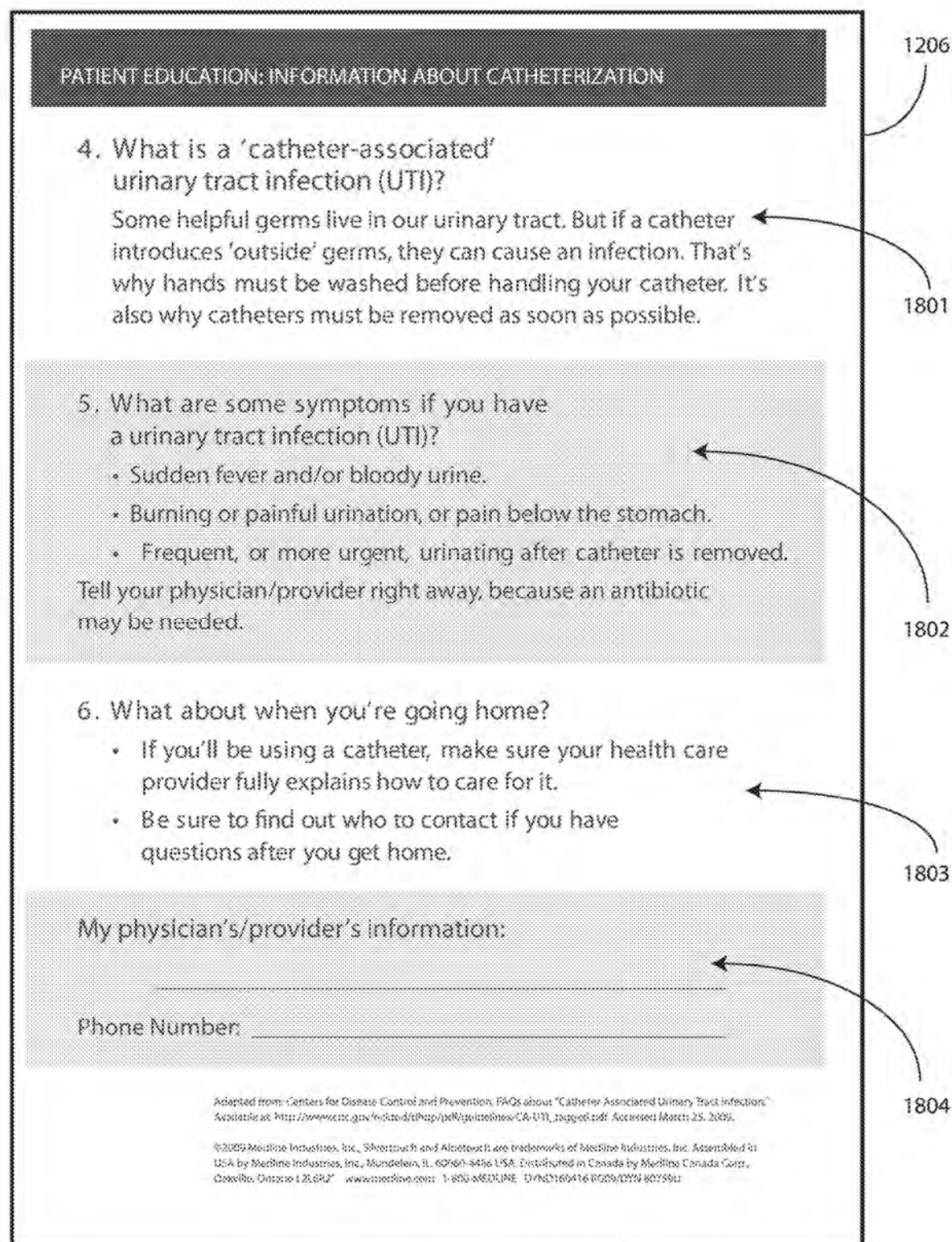
FIG. 13

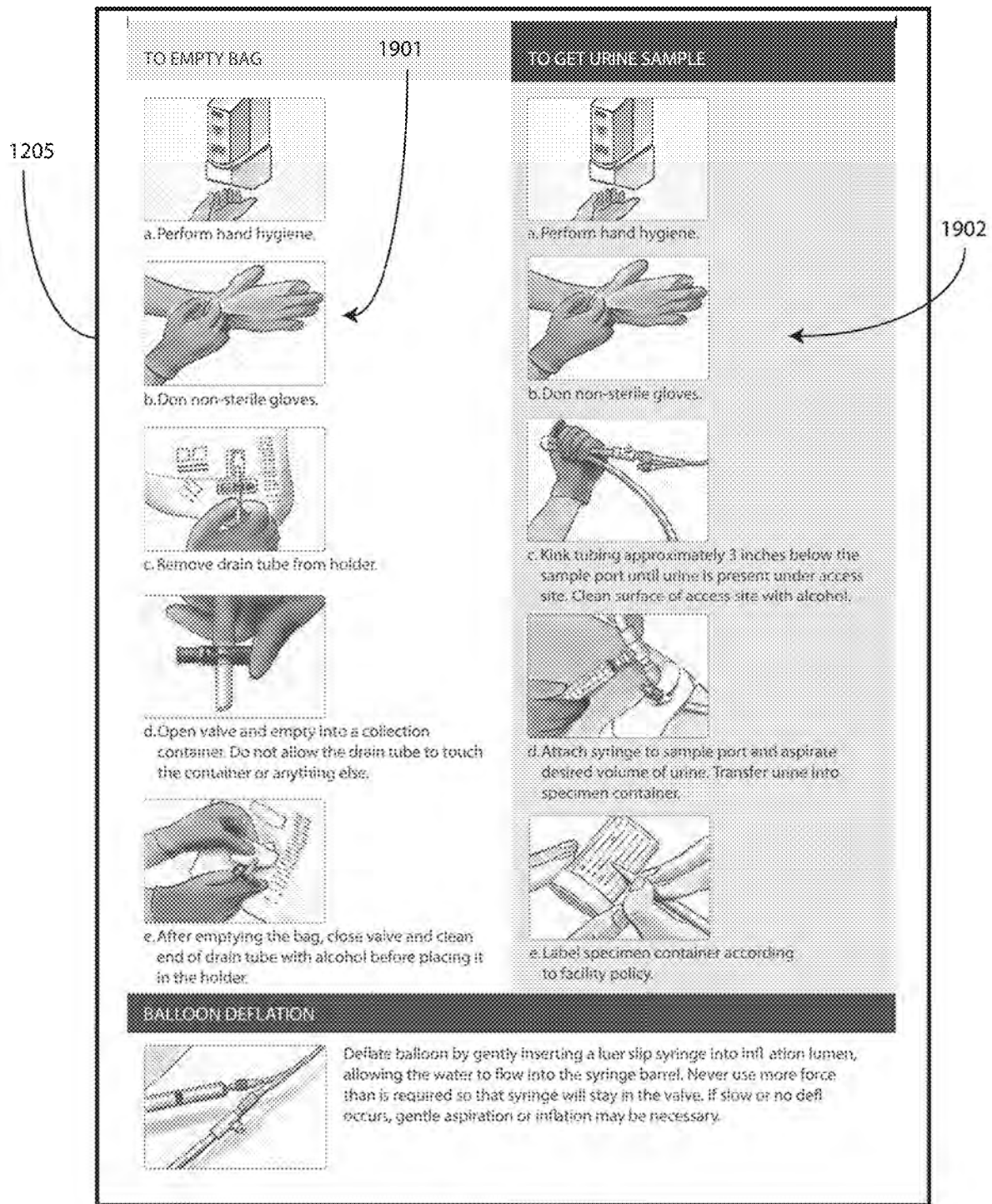
**FIG. 14**

**FIG. 15**

**FIG. 16**

**FIG. 17**

**FIG. 18**

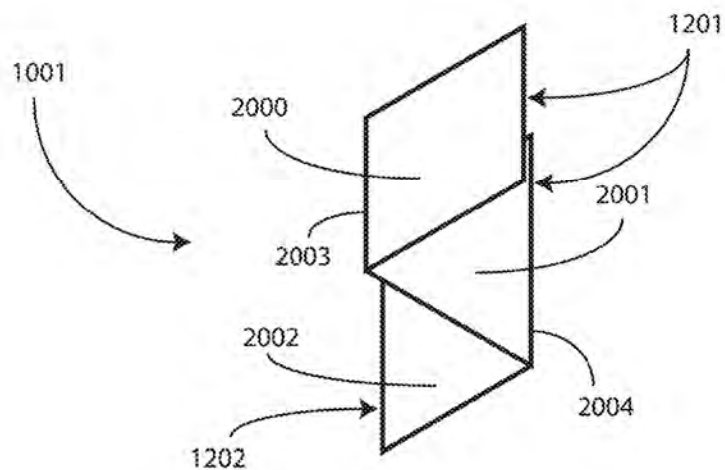
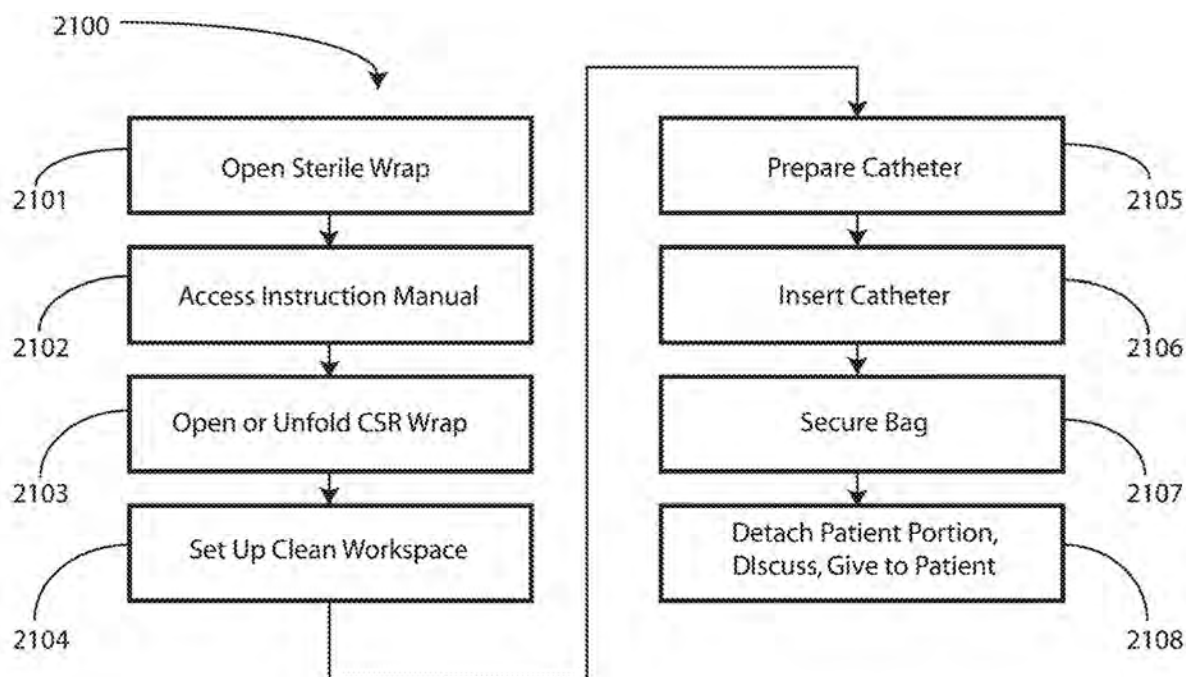
**FIG. 19**

U.S. Patent

May 30, 2023

Sheet 17 of 35

US 11,661,220 B2

**FIG. 20****FIG. 21**

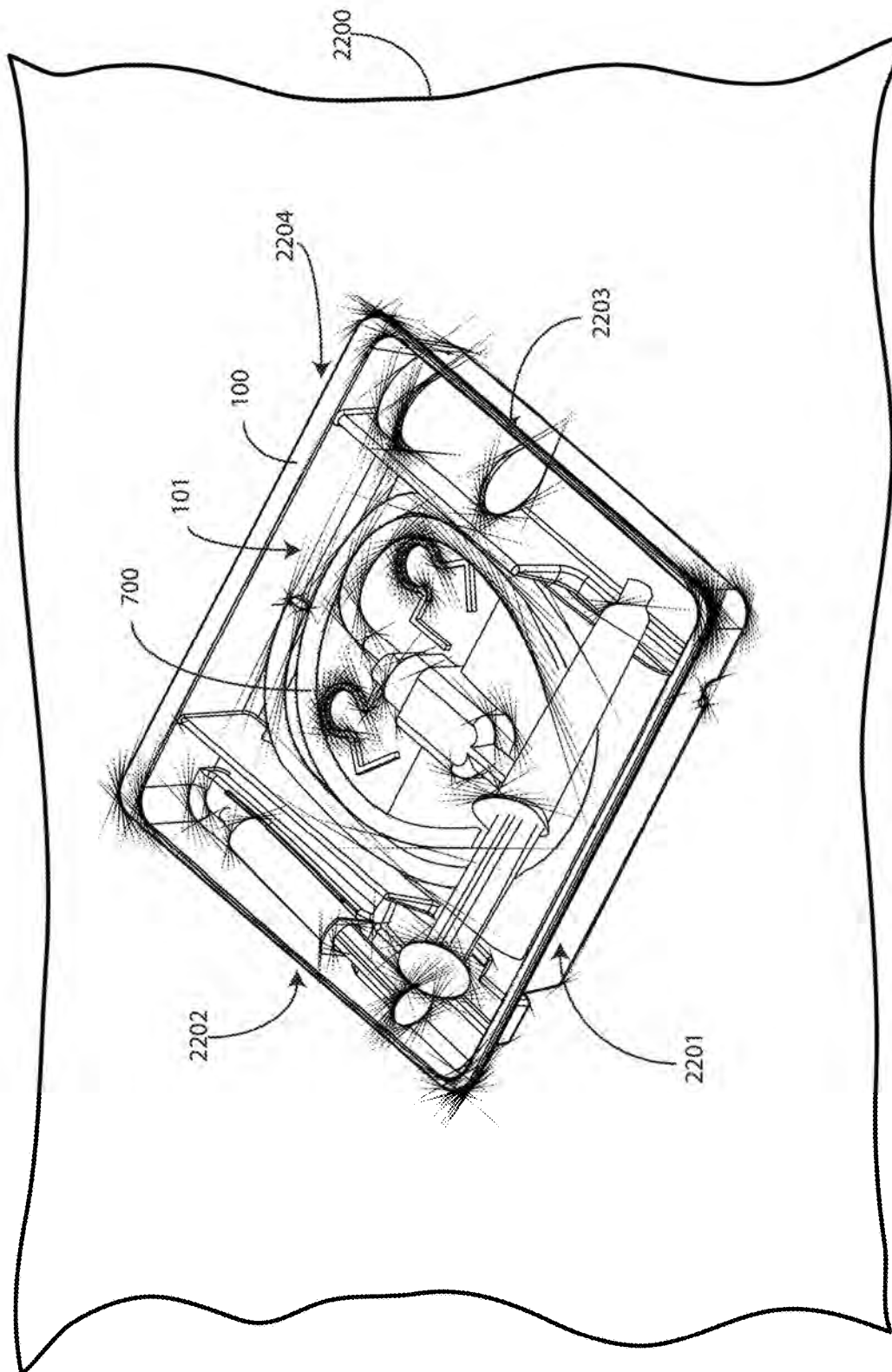
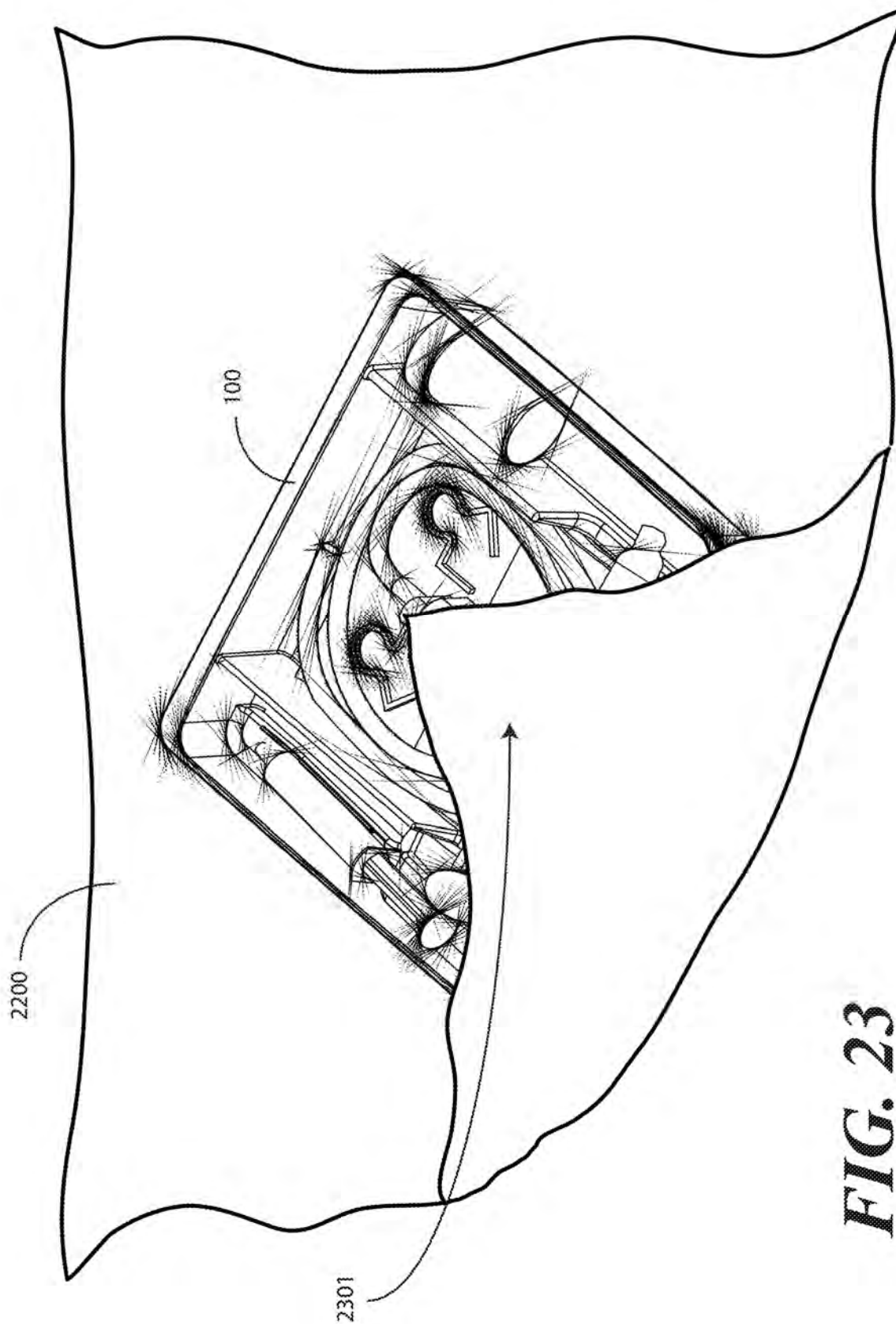
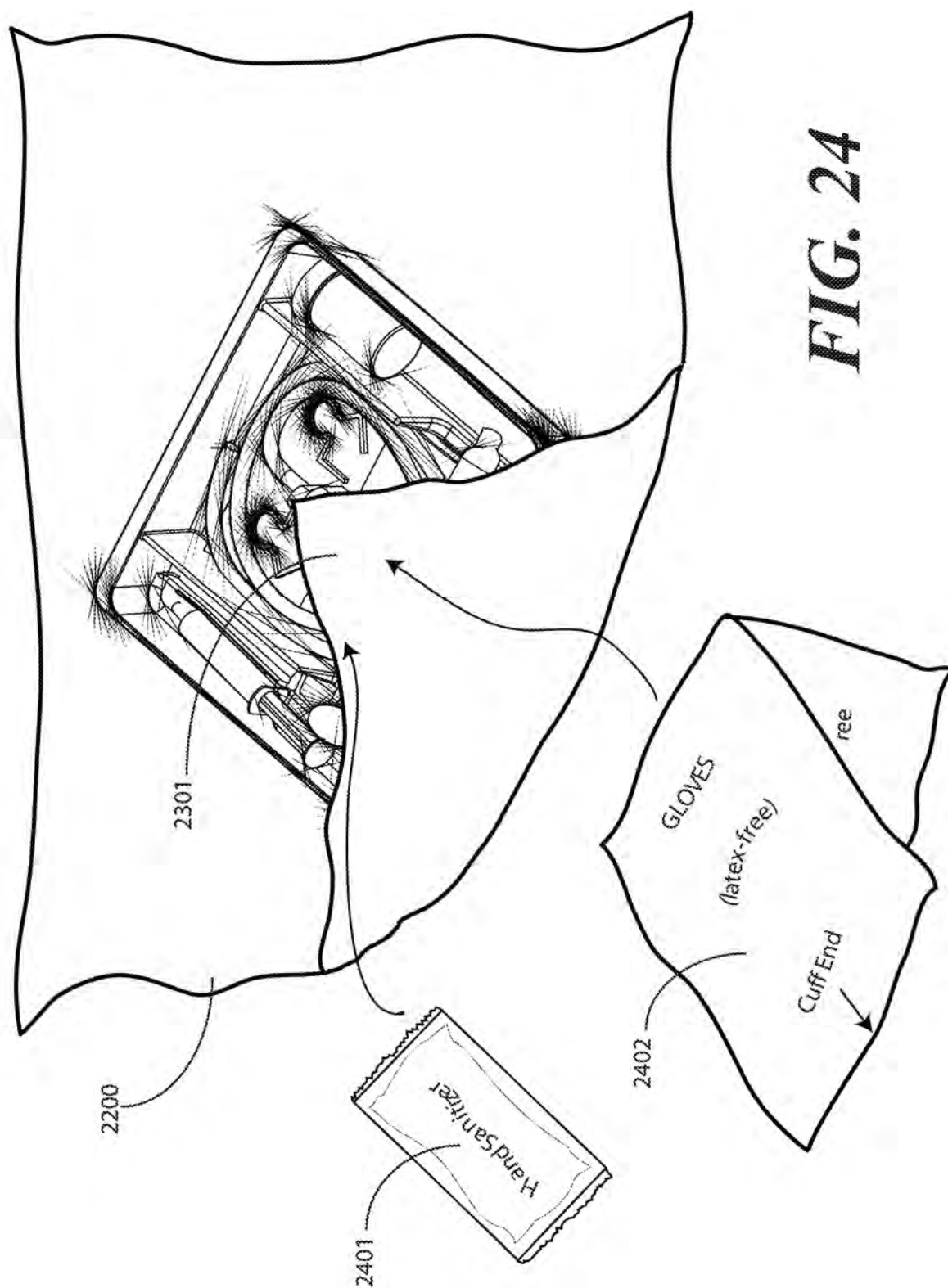


FIG. 22





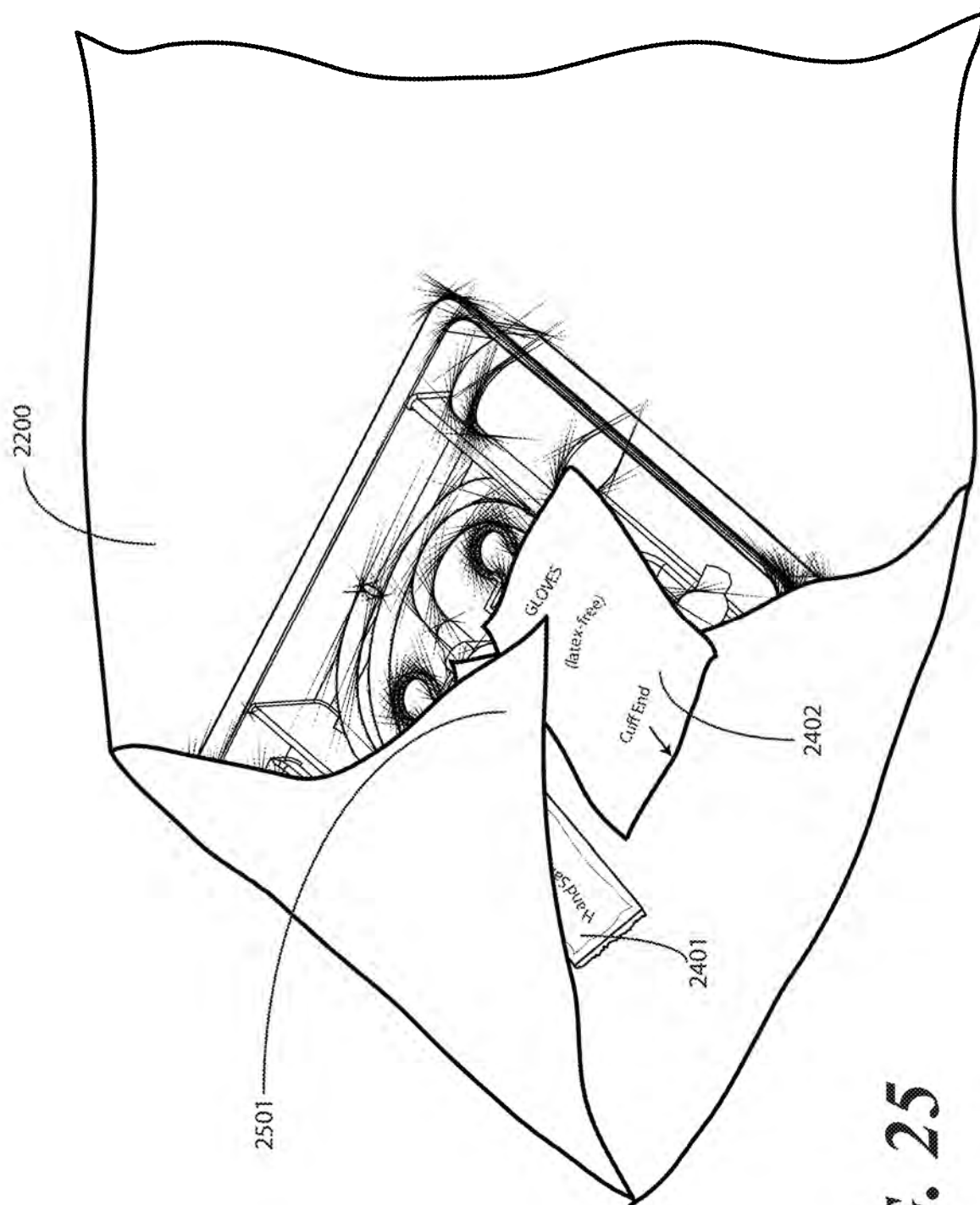


FIG. 25

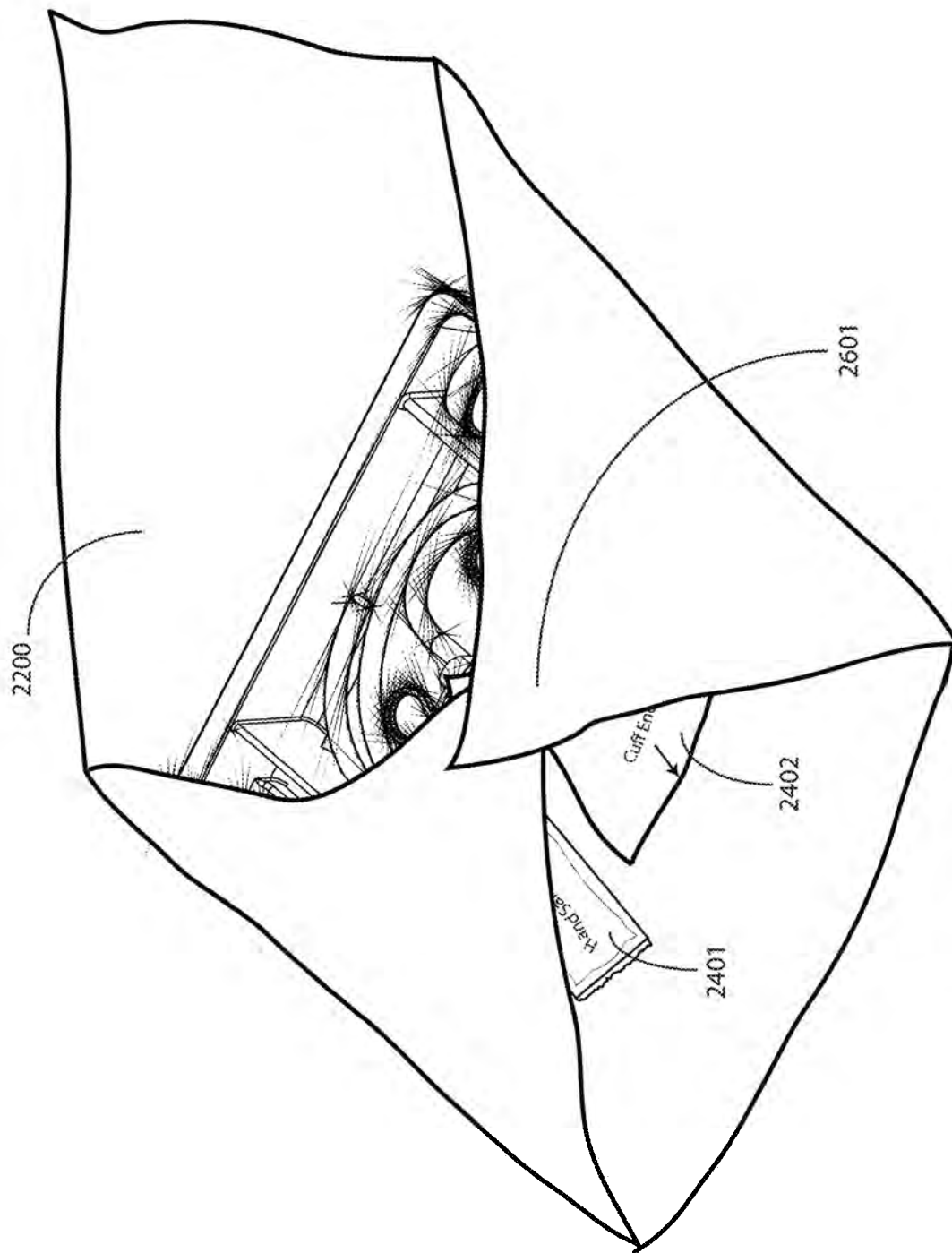


FIG. 26

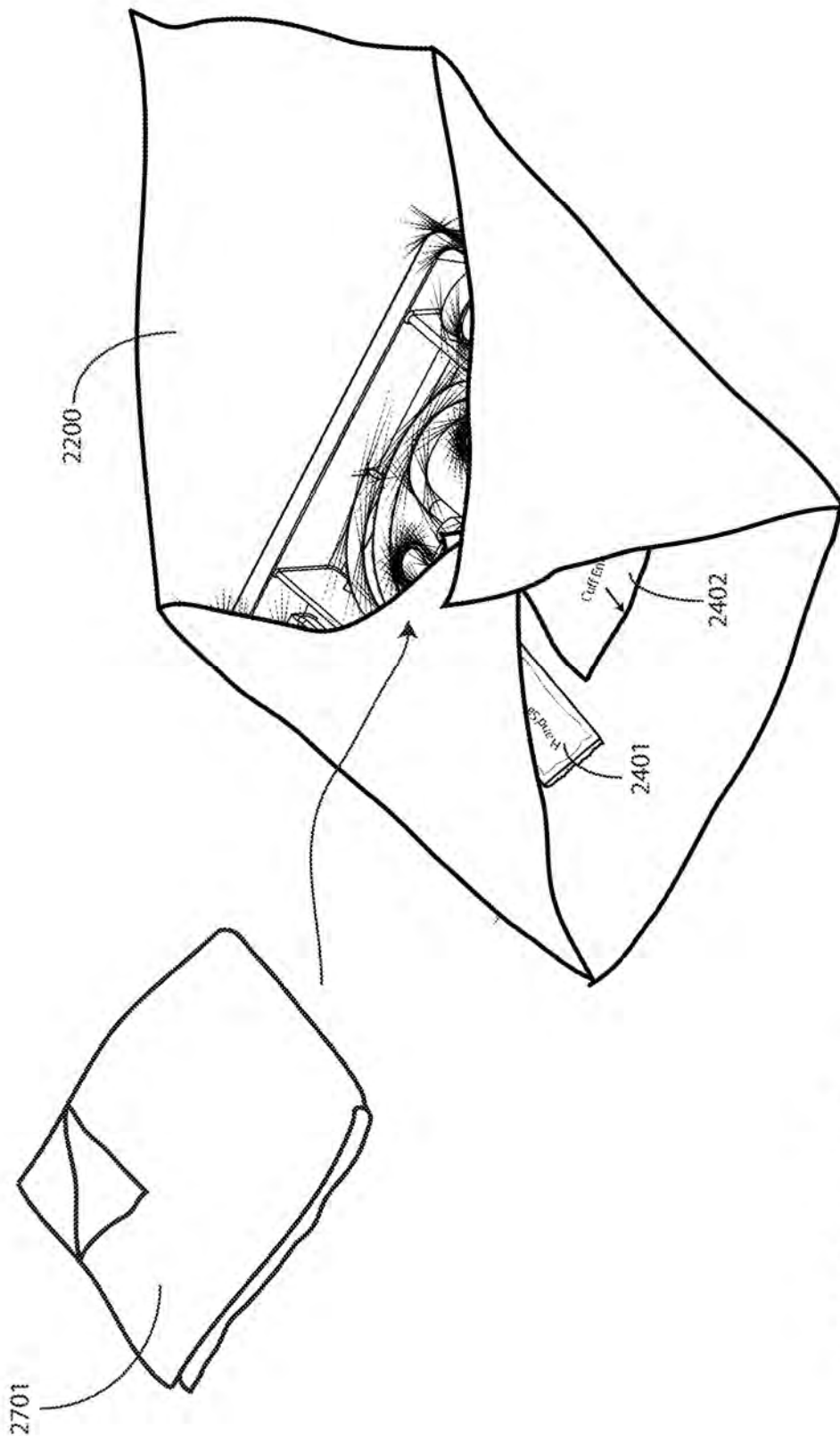


FIG. 27

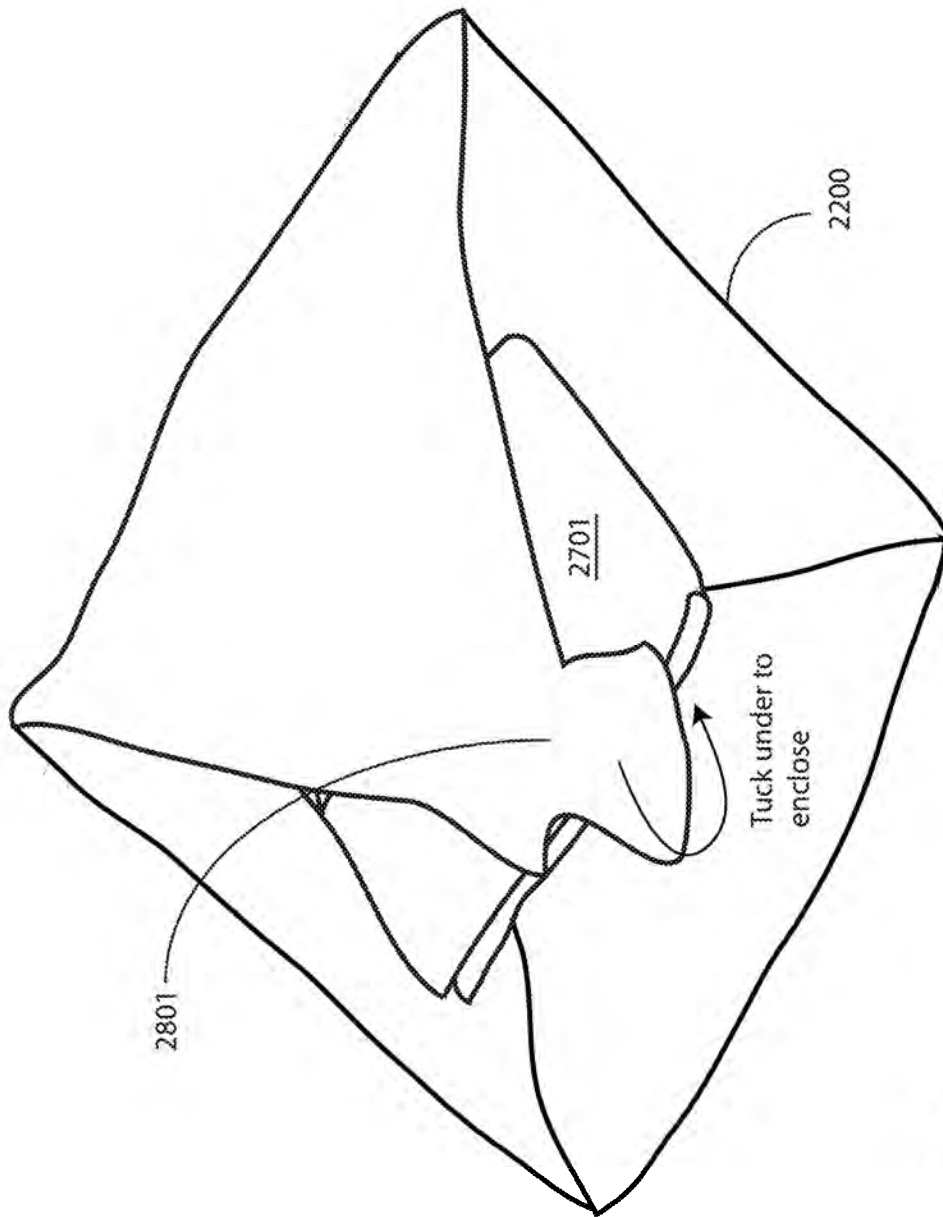


FIG. 28

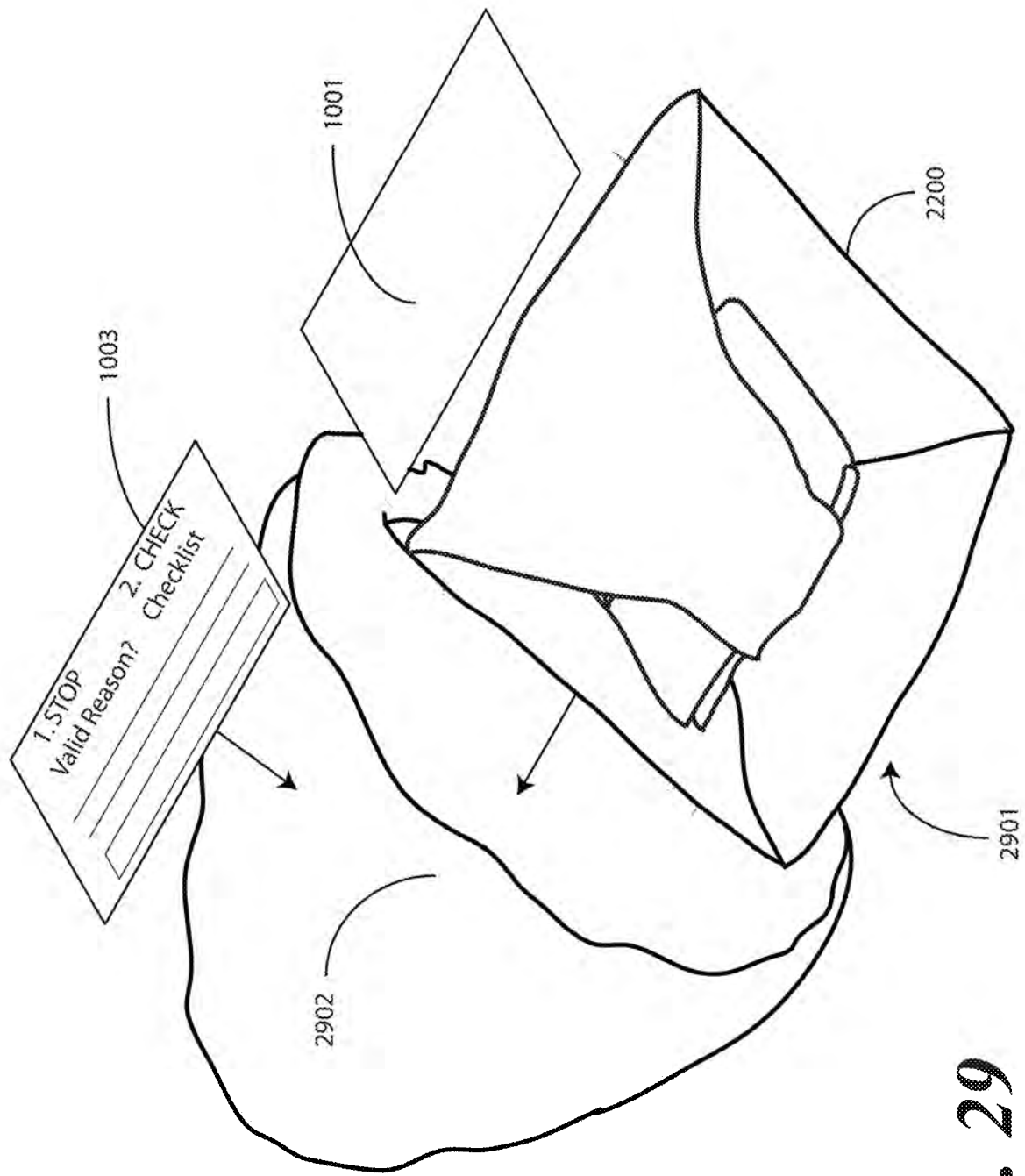


FIG. 29

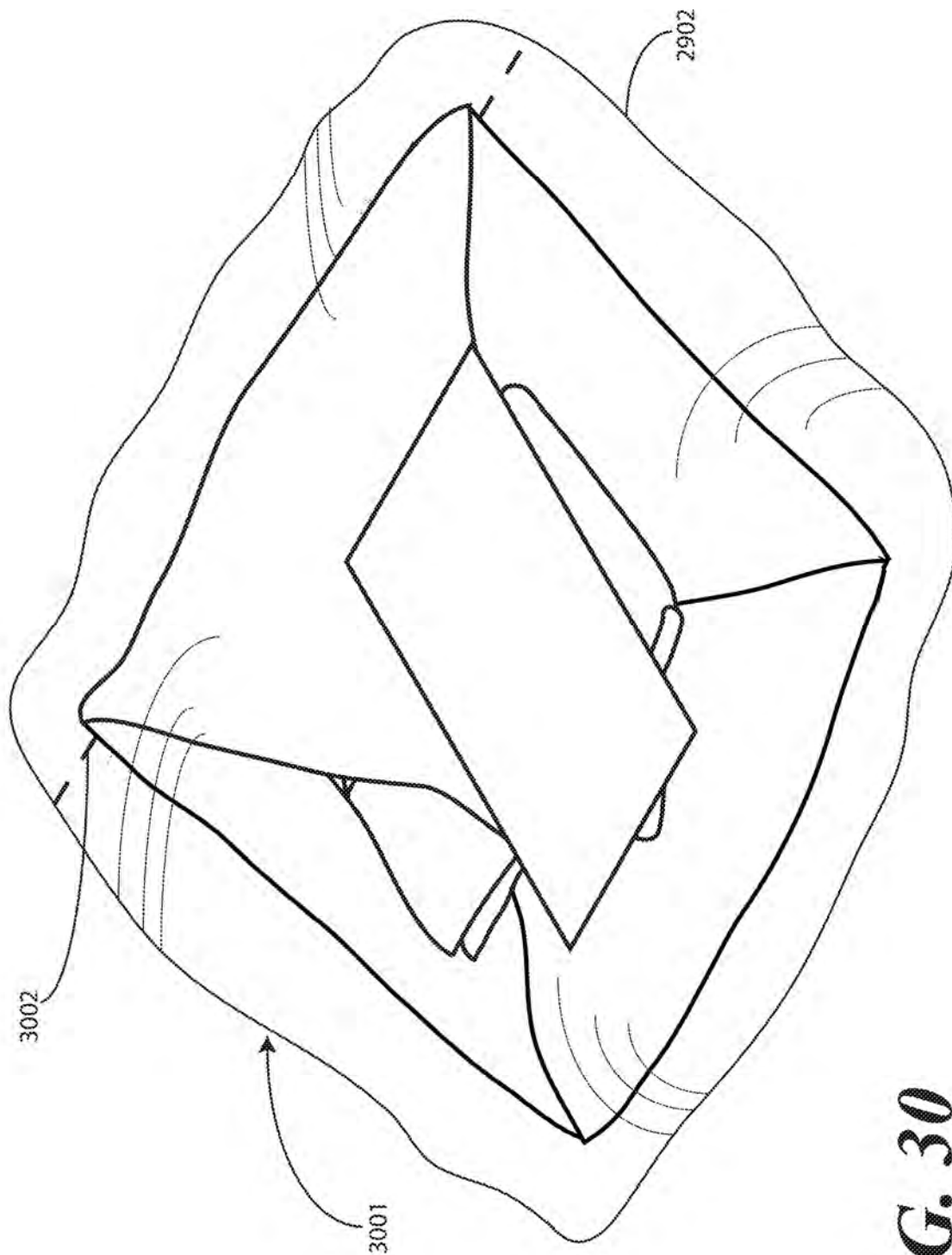
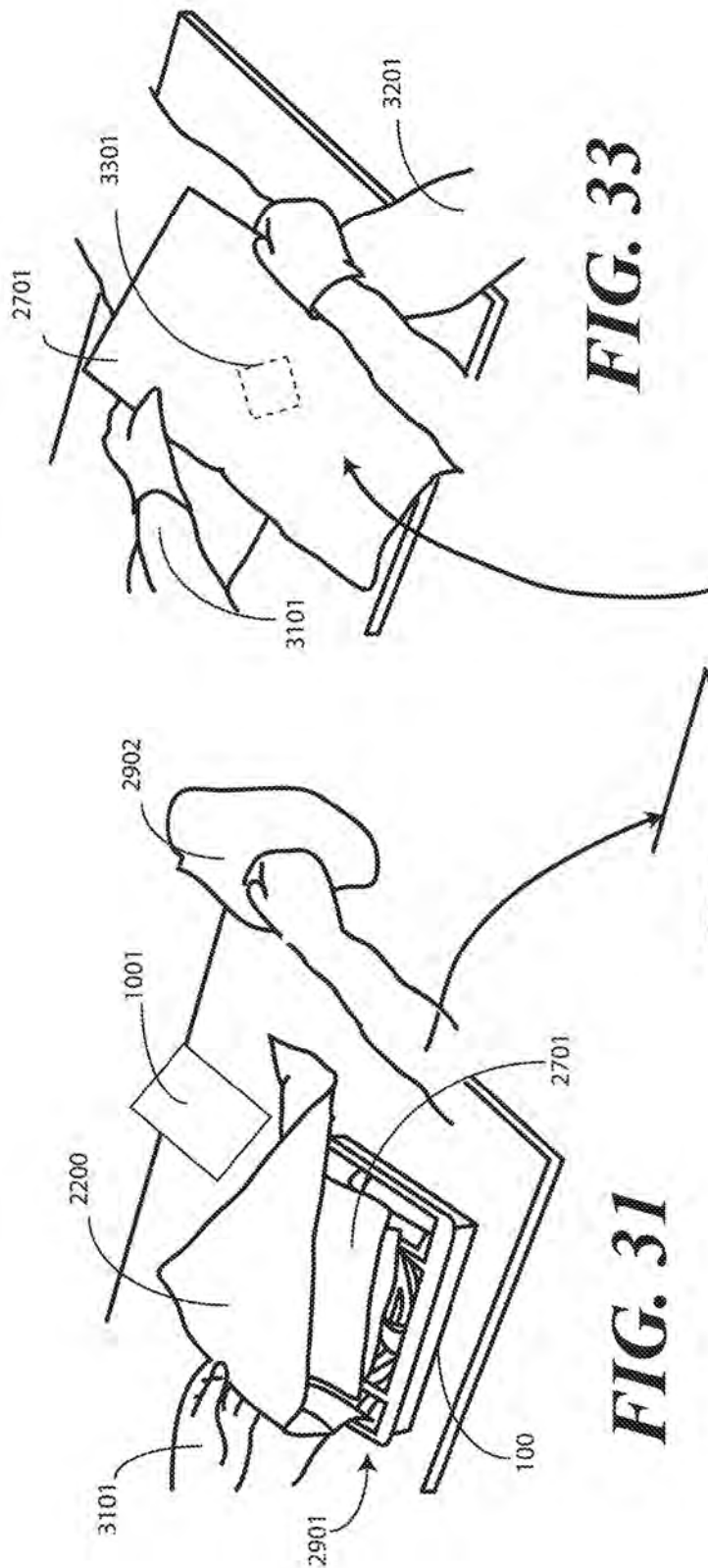


FIG. 30



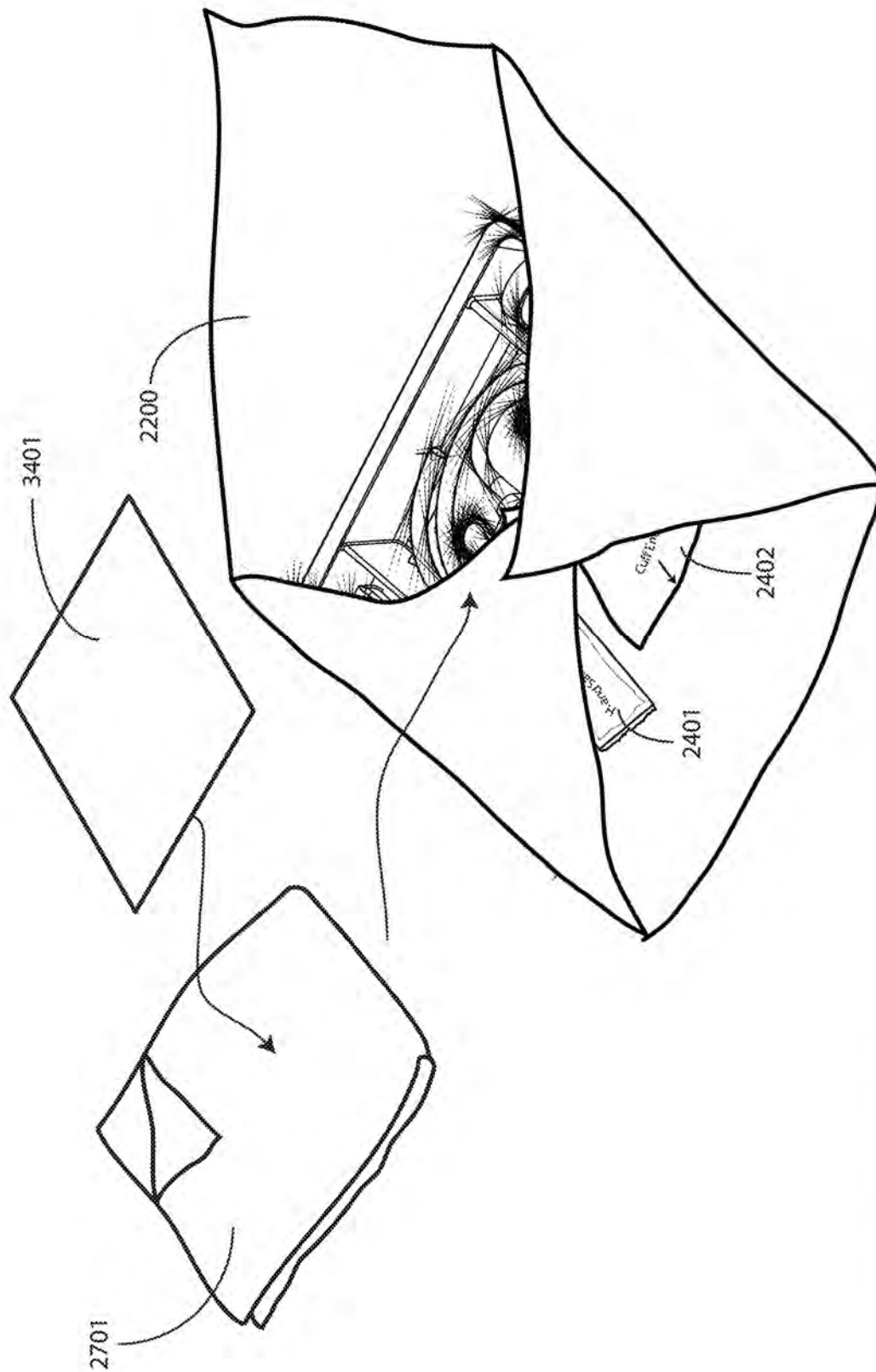


FIG. 34

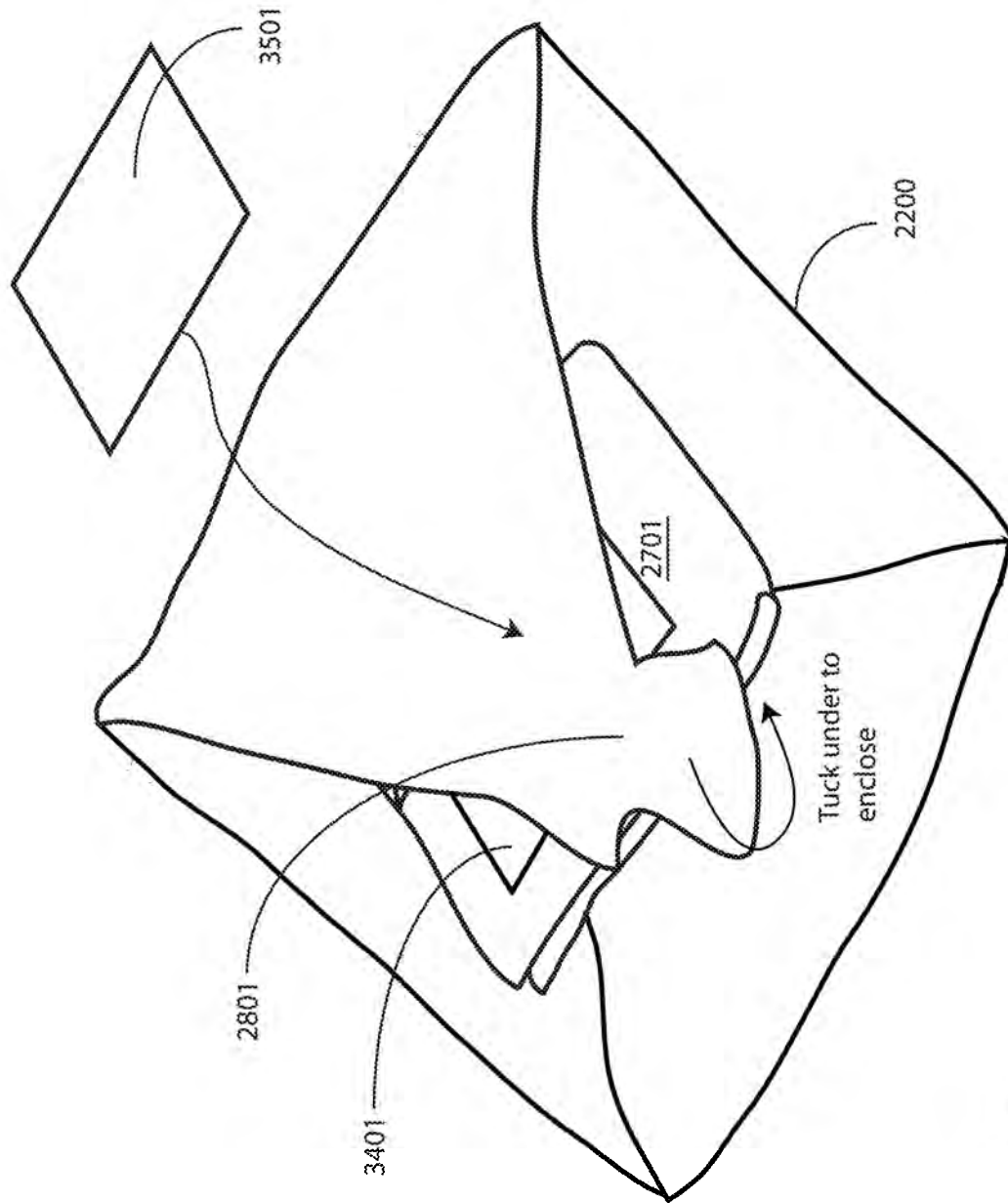


FIG. 35

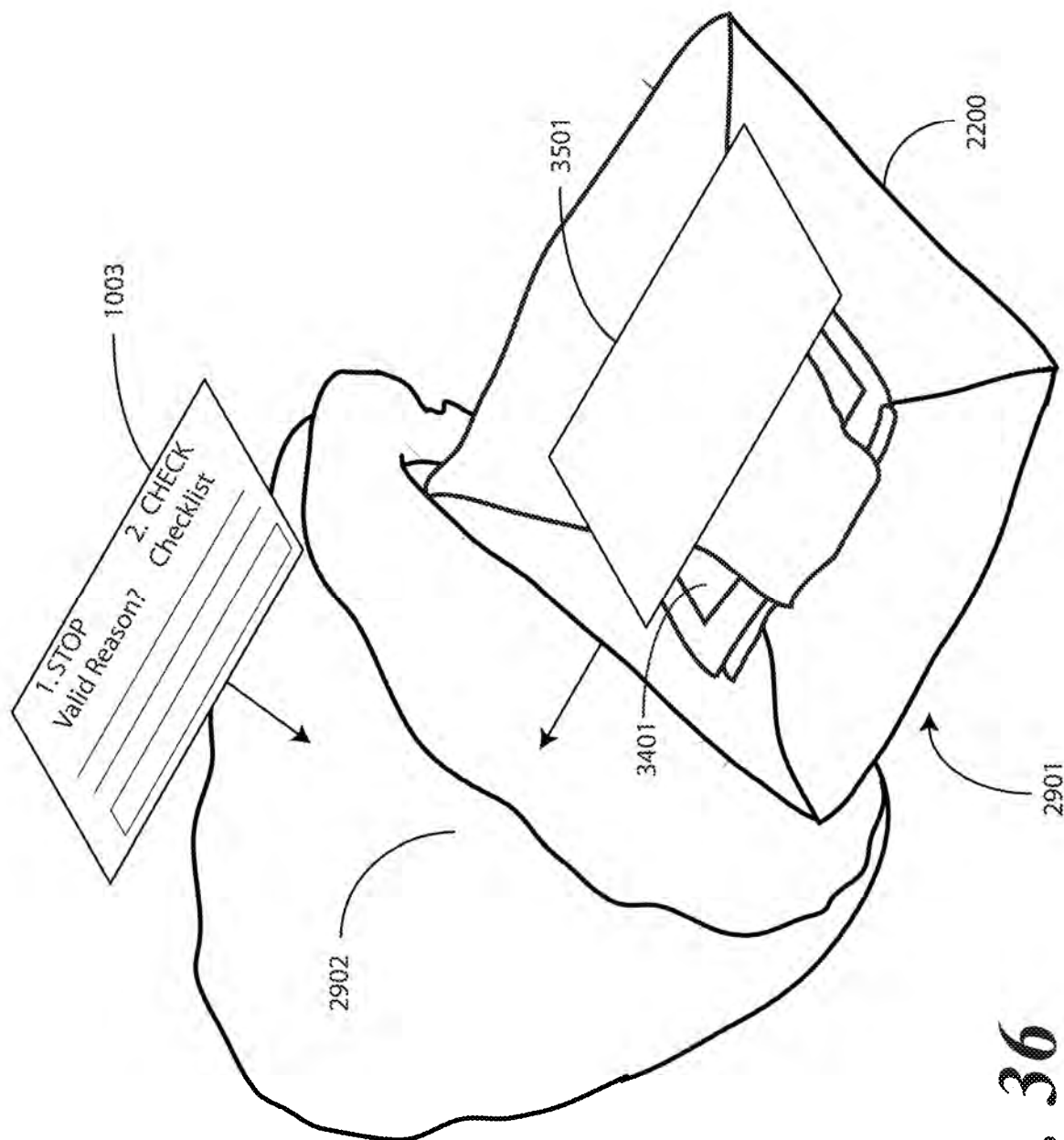


FIG. 36

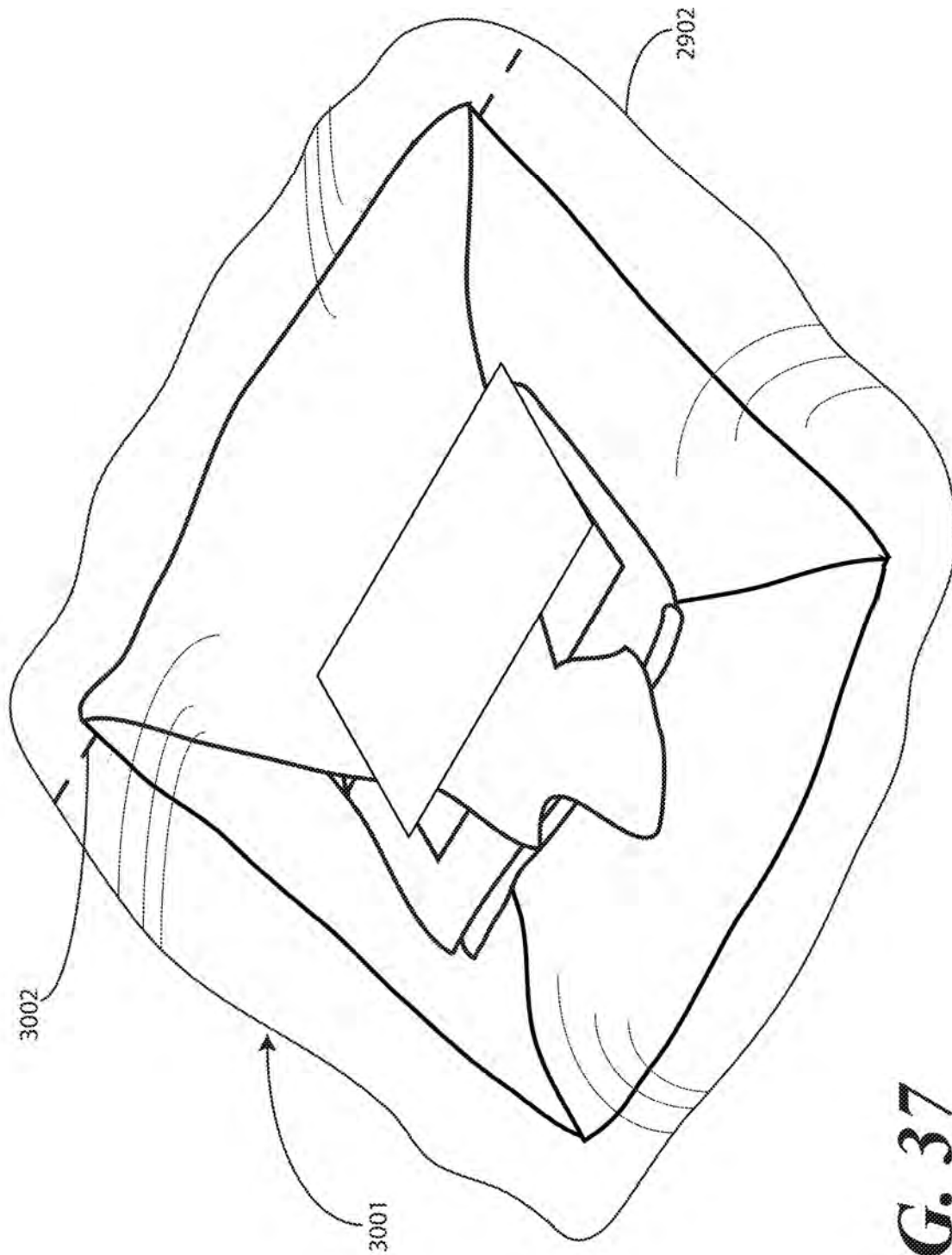
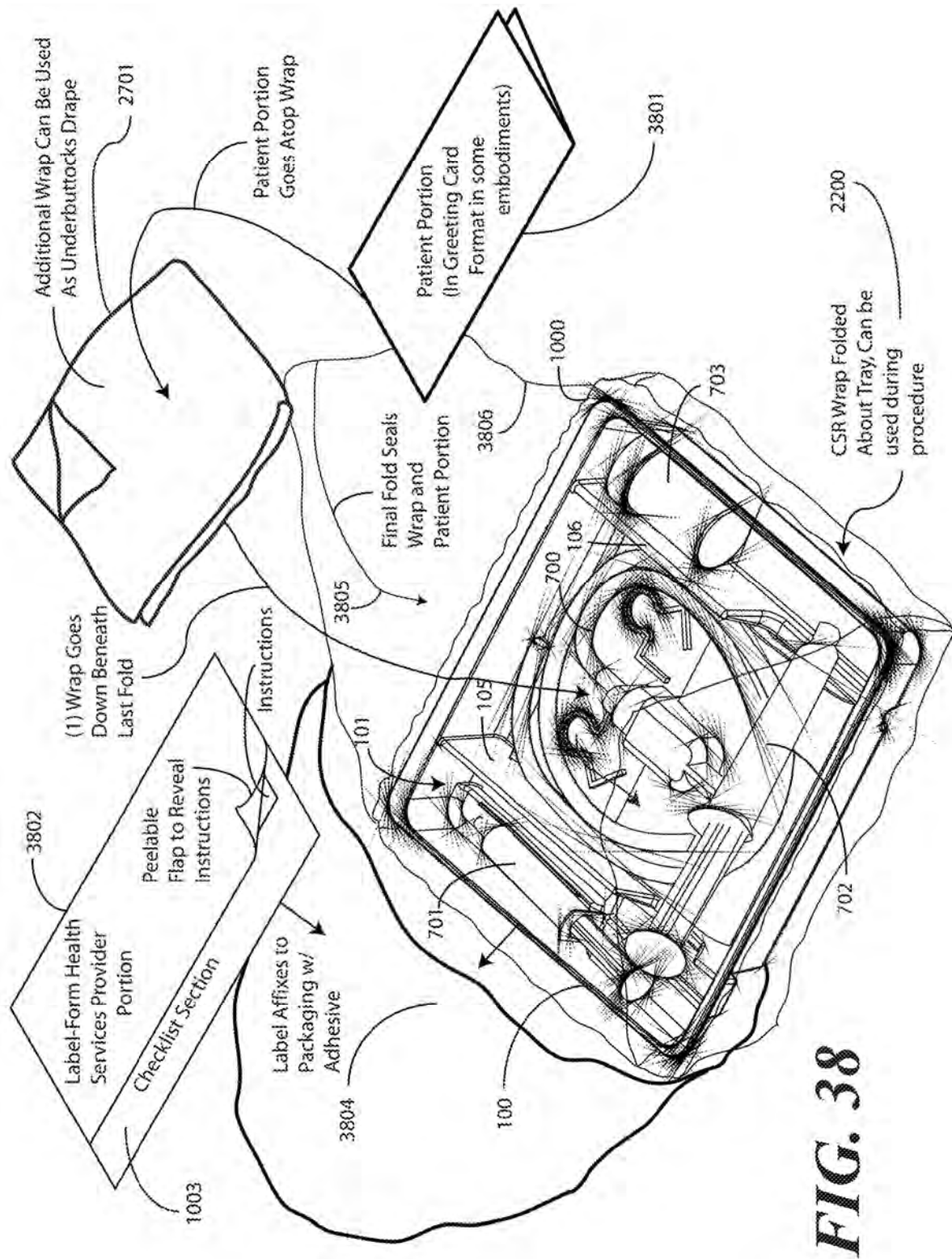


FIG. 37



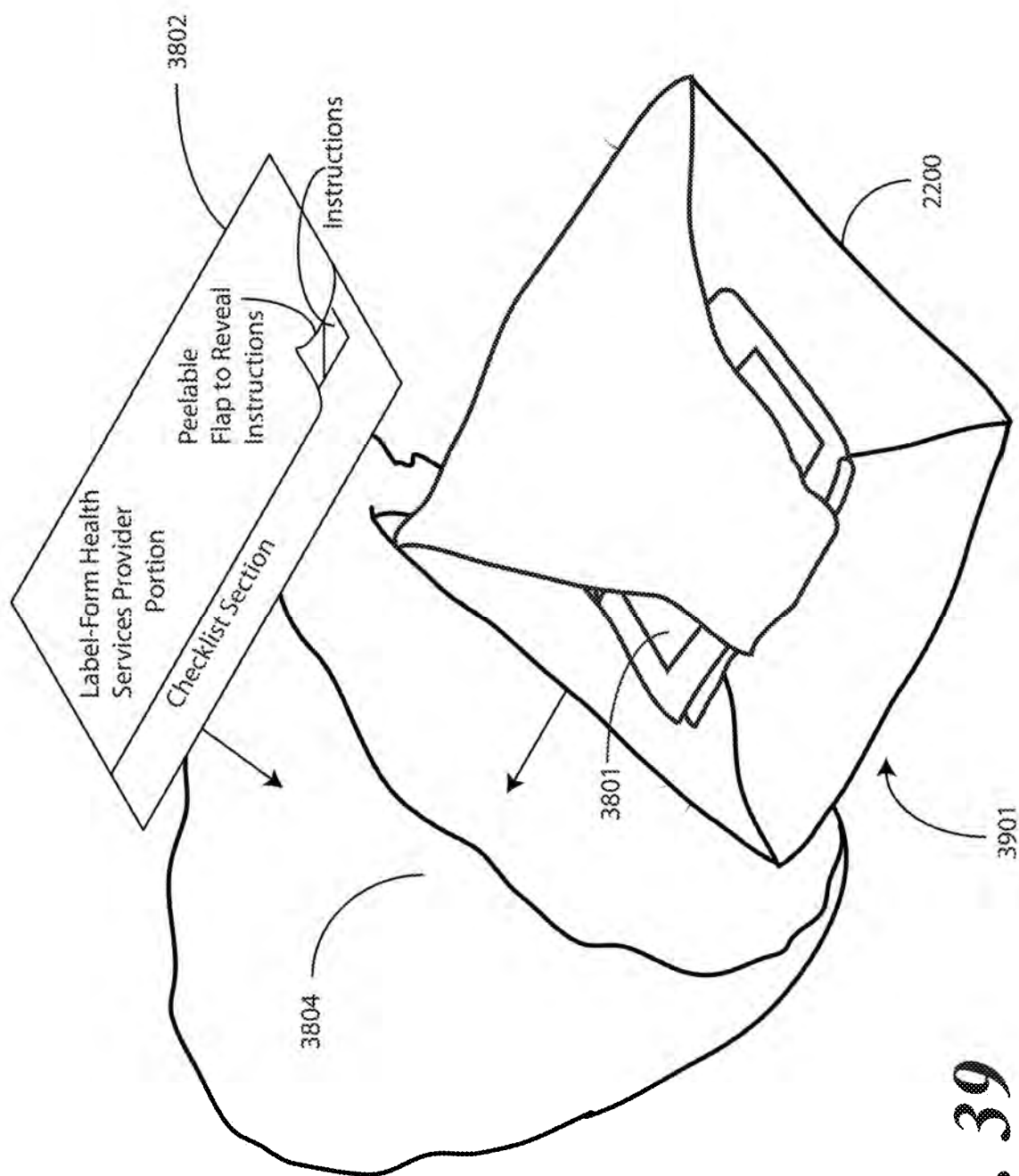


FIG. 39

U.S. Patent

May 30, 2023

Sheet 34 of 35

US 11,661,220 B2

4004 LATEX FOLEY CATHETER TRAY 14Fr 10ml REF DYND160114

ERASE CAUTI Tray Pre-Connected with Silicone-Elastomer coated Latex Foley Catheter and Drainage Bag

4003

4000

4005

CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

STERILE

Contents of all package have not been terminally sterilized. Rx Only single Use Only.

DATE & TIME OF INSERTION: NAME: SIGNATURE:

4006

1. STOP: IS THERE A VALID CLINICAL REASON?

BEFORE INSERTING A FOLEY CATHETER, AT LEAST ON OF THE FOLLOWING CONDITIONS EXISTS:

☐ Select surgical procedures
☐ Prolonged immobilization
☐ End-of-life care

☐ Acute urinary retention or obstruction
☐ Precise measurement of urinary output
☐ Open wounds in incontinent patient

2. CHECK: INSERTION CHECKLIST

CHECK EACH BOX UPON COMPLETION:

☐ Obtain order from physician/provider
☐ Document clinical reason for insertion
☐ Use the smallest catheter possible
☐ Follow aseptic technique

☐ Explain procedure to the patient
☐ Perform hand hygiene
☐ Provide patient education

UNLATCH AND PEEL OFF THIS STICKER AND KEEP WITH MEDICAL RECORDS

4002

4007

STEP-BY-STEP GUIDE AND TIPS INSIDE

OPEN HERE

(01)108643892528

FIG. 40

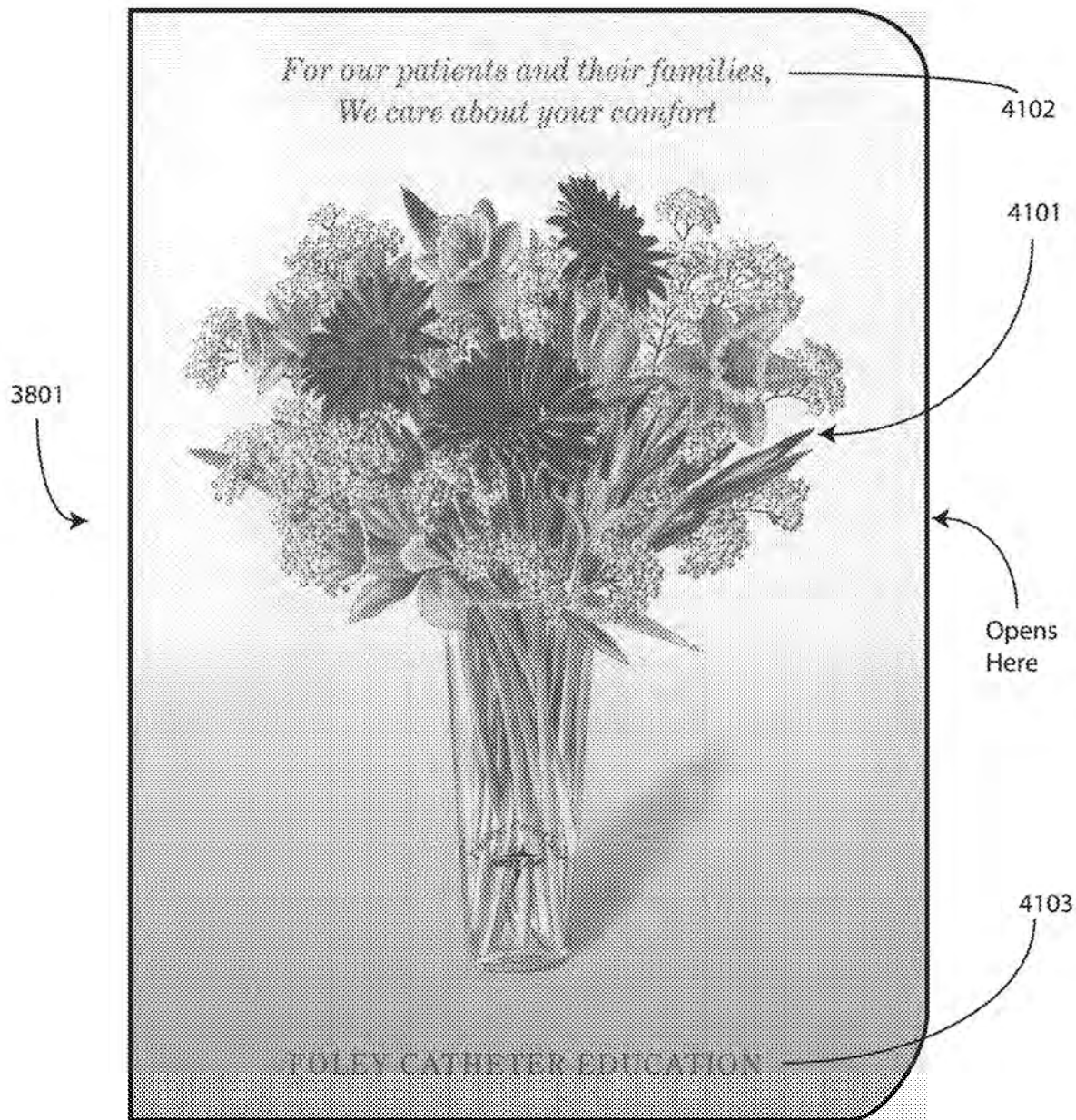


FIG. 41

US 11,661,220 B2

1

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS

CROSS REFERENCE TO PRIOR APPLICATIONS

This application is a continuation application claiming priority to Ser. No. 16/833,575, filed Mar. 28, 2020, which is a continuation application claiming priority to Ser. No. 15/684,787, filed Aug. 23, 2017, which is a continuation application claiming priority to Ser. No. 14/793,455, filed Jul. 7, 2015, which is a continuation application claiming priority to Ser. No. 13/860,902, filed Apr. 11, 2013, which is a divisional application from Ser. No. 13/155,026, filed Jun. 7, 2011, which claims priority and benefit under 35 U.S.C. § 119(e) from U.S. Provisional Applications: Ser. No. 61/352,140, filed Jun. 7, 2010; Ser. No. 61/352,155, filed Jun. 7, 2010; Ser. No. 61/428,944, filed Dec. 31, 2010; and Ser. No. 61/437,796, filed Jan. 31, 2011, each of which is incorporated herein by reference. Moreover, Ser. No. 13/155,026 is further a continuation in part of: Ser. No. 12/495,148, filed Jun. 30, 2009, which claims priority and benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application: Ser. No. 61/183,629, filed Jun. 3, 2009; Ser. No. 12/647,515, filed Dec. 27, 2009; Ser. No. 13/153,265, filed Jun. 3, 2011; and Ser. No. 13/153,300, filed Jun. 3, 2011, each of which is incorporated herein by reference. As the present application claims priority to Ser. No. 13/155,026 through Ser. No. 14/793,455 and Ser. No. 13/860,902, the present application also, by law, claims priority to each of Ser. No. 12/495,148, Ser. No. 12/647,515, Ser. No. 13/153,265, and Ser. No. 13/153,300 through its priority claim to Ser. No. 13/155,026.

This application is related to commonly assigned U.S. Pat. No. 7,624,869 to Primer, which is incorporated herein by reference. This application is related to commonly assigned U.S. patent application Ser. No. 12/004,796, filed Dec. 21, 2007, which is incorporated herein by reference.

BACKGROUND

Technical Field

This invention relates generally to storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices, as well as an instruction manual included therewith.

Background Art

Medical devices, including surgical instruments, supplies, and so forth, are generally shipped from manufacturer to medical services provider in sterile packaging. For example, a scalpel may be shipped to a surgeon in a plastic, vacuum-sealed, sterile package. Similarly, bandages may be shipped in paper, plastic, or paper composite sterile wrappers. When the medical services provider is ready to use the medical supply, the sterile package is removed. The medical services provider then uses the object in accordance with the procedure being performed.

While conventional packaging works well for objects having a generally unchanging form factor, special considerations have to be taken into consideration for some medical supplies. By way of example, catheter assemblies and other flexible equipment is generally shipped in a coiled

2

configuration. Once the sterile packaging is removed, the catheter must be uncoiled prior to use. Care must be taken in shipping, unwrapping, and using the catheter. For instance, if a catheter is inadvertently bent, kinked, or otherwise damaged, it may no longer be suitable for use. Compounding this issue, catheters are available in a variety of lengths ranging from 100 centimeters to over 250 centimeters.

Traditional catheters are packaged, for example, in individual packaging. The catheter and card are then sealed in a sterile plastic wrap. These catheters are prone to damage in shipment, storage, and when being unpacked, as the card and wrap provide little physical protection.

Some manufacturers have started shipping catheters and other similar devices in flat plastic trays. For example, U.S. Pat. No. 6,068,121 to McGlinch teaches one such tray. The tray has several specifically contoured loops such that one universal tray will accommodate several different sized catheters. Such packaging presents a problem, however, in that large amounts of storage space are taken with a universal tray, especially when a relatively short catheter is shipped therein. Additionally, when in use, these trays occupy large amounts of a medical service provider's sterile workspace or table, leaving little room for related components, such as lubricants, fluid bags, and so forth.

There is thus a need for an improved container for flexible medical devices or catheters that facilitates more effective and simpler deployment of the device during a procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views and which together with the detailed description below are incorporated in and form part of the specification, serve to further illustrate various embodiments and to explain various principles and advantages all in accordance with the present invention.

FIG. 1 illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 2 illustrates a top, front, left perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 3 illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 4 illustrates a front elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 5 illustrates a cut-away, left elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 6 illustrates a bottom plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. 7 illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. 8 illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. 9 illustrates a transparent, front elevation view of one embodiment of a tray for a catheter or similar assembly,

US 11,661,220 B2

3

with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. 10 illustrates a perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, along with instructions and packaging, in accordance with embodiments of the invention.

FIG. 11 illustrates a method of manufacturing one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. 12 illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

FIG. 13 illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

FIGS. 14-19 illustrate exemplary panels of printed instructions in accordance with embodiments of the invention.

FIG. 20 illustrates a physical configuration of printed instructions in accordance with one embodiment of the invention.

FIG. 21 illustrates a method in accordance with embodiments of the invention.

FIGS. 22-30 illustrate various stages of a method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. 31-33 illustrate various stages of a method of deploying a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. 34-37 illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. 38-39 illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIG. 40 illustrates an alternate health care services provider portion of printed materials configured as an adhesive label with an opening flap in accordance with one embodiment of the invention.

FIG. 41 illustrates an alternative patient portion of printed instructions configured as a greeting card and having patient information therein, in accordance with one embodiment of the invention.

Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention are now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. As used in the description herein and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of "a," "an," and "the" includes plural reference, the meaning of "in" includes "in" and "on." Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. Also, reference designators shown herein in parenthesis indicate com-

4

ponents shown in a figure other than the one in discussion. For example, talking about a device (10) while discussing figure A would refer to an element, 10, shown in figure other than figure A.

Embodiments of the present invention provide a medical procedure kit that includes medical products for performing a medical procedure. In one embodiment, the medical procedure kit is configured for a catheterization procedure. Such an embodiment will be used herein for illustration purposes. However, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other medical procedure kits for performing other procedures could be substituted for the illustrative catheterization tray disclosed herein by substituting other medical implements for the catheterization implements. In the illustrative embodiment, a tray is configured to accommodate a medical device or assembly. In an illustrative embodiment, the medical device is a coiled device, such as a catheter or catheter assembly. In addition to accommodating the coiled medical device, embodiments of the present invention are also configured to contain devices and materials intended for use with the coiled medical device.

Using a catheter assembly as an example, when a catheter assembly is inserted into a patient, sterile water may be used to inflate the catheter. Additionally, the catheter may be coated in a lubricating jelly prior to insertion into the patient. Fluids and other samples may then be monitored and obtained from the patient via the catheter. Embodiments of the present invention provide a single container configured to accommodate not only the catheter assembly and fluid bag, but also syringes containing sterile water or lubricants. Further, the tray can accommodate a sterile specimen jar for capturing samples taken from the patient via the catheter.

In addition to simply accommodating these corresponding medical devices, in one embodiment the tray is configured to provide the medical services provider with mnemonic devices instructing them in which order to use each device. For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use.

Another advantage of embodiments of the present invention is that compartments have multi-purpose functionality. For example, in one embodiment, a container configured to accommodate a syringe having lubricating jelly disposed therein is also configured to be used as a lubricating jelly applicator. A medical services provider first dispenses the lubricating jelly into the syringe compartment. The medical services provider then passes the catheter from another compartment through an opening in a barrier separating the compartments into the lubricating jelly. As such, the tray not only serves as a shipping and storage container for an assembly of devices used with a catheter procedure, but also as an application device to assist a medical services provider in using those products together.

Turning now to FIGS. 1-6, illustrated therein are views of one embodiment of a tray 100 configured to accommodate a catheter assembly in accordance with embodiments of the invention. FIG. 1 illustrates a top, front right perspective view of the tray 100. FIG. 2 illustrates a top, front, left perspective view of the tray 100. FIG. 3 illustrates a top plan view of the tray 100. FIG. 4 illustrates a front elevation view of the tray 100. FIG. 5 illustrates a cut-away, left elevation view of one embodiment of a tray 100. Likewise, FIG. 6 illustrates a bottom plan view of the tray 100. For simplicity of discussion, these figures will be referred to collectively

US 11,661,220 B2

5

with like reference numerals referring to identical or functionally similar elements throughout the separate views.

The tray 100, in one embodiment, is formed by a contoured surface 104 that defines the various features and compartments of the tray 100. The contoured surface 104 of the tray 100 can be manufactured in various ways. For example, in one embodiment, the tray 100 can be thermally formed on a mold from a soft thermoplastic, such as styrene or polystyrene. In another embodiment, the tray 100 can be injection molded. In another embodiment, the tray can be poured on a mold using a quick setting plastic, epoxy, or resin. Other methods of manufacture will be obvious to those of ordinary skill in the art having the benefit of this disclosure.

Exemplary dimensions for one embodiment of the tray 100 are as follows: The length 112 can be between nine and twelve inches, such as ten inches. One illustrative length 112 may be 10.380 inches. Similarly, the width 113 can be between eight and eleven inches, such as nine inches. One illustrative width 113 is 9.250 inches. The height 114 can be between one and three inches. One illustrative height 114 is 1.750 inches.

In one embodiment, the tray 100 includes three main compartments: a first compartment 101, a second compartment 102, and a third compartment 103. The first compartment 101 is separated from the second compartment 102 by a first barrier 105. The second compartment 102 is separated from the third compartment 103 by a second barrier 106.

In one embodiment, the compartments are open from the top of the tray 100—the top being opposite the base members of the tray 100—and are bounded on the bottom by a first base member 107, a second base member 108, and a third base member 109. The compartments are bounded on the sides by a perimeter wall 110. In the illustrative “open top” embodiment of FIG. 1, the perimeter wall 110 ends in a horizontal flange 111 extending substantially orthogonally from the perimeter wall 110. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments other than that shown in FIG. 1 are possible without departing from the spirit and scope of the invention. For instance, the top of the tray 100 could have a hinged or snap-coupled lid that is opened or removed to reveal the compartments there beneath.

In one illustrative embodiment, the tray 100 is configured to hold or otherwise accommodate all of the necessary devices and materials to perform a catheter-based procedure on a patient. Said differently, the tray 100 is configured to hold not only the catheter assembly, but the medical devices corresponding to catheter use as well. Using one illustrative procedure as an example, the following devices will be used: a syringe holding sterile water, a syringe holding lubricating jelly or another equivalent lubricant, a catheter assembly, skin cleansing or preparation materials, and a specimen jar. The various compartments and features of the tray 100 shown in FIGS. 1-6 will be described for use with these devices. As will be described in more detail below, additional objects can be included with the tray, such as one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, swab sticks, a securement device, a Foley insert tag, a printed instruction pamphlet, and so forth. The syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar are used for illustration purposes only, as it will be clear that other objects may be added to or substituted for these objects. Further, subsets of these objects may be used.

In one embodiment suitable for procedures using the syringe holding sterile water, syringe holding lubricating

6

jelly, catheter assembly, and specimen jar, in one embodiment, the tray 100 is configured such that these objects are ordered in accordance with their use during the procedure. For example, in one embodiment the tray 100 includes a first compartment 101 for accommodating one or more syringes, a second compartment 102 for accommodating the catheter assembly, and a third compartment 103 for accommodating the specimen jar. These devices stowed in the various compartments will be illustrated and described with respect to FIGS. 7-10 below. The discussion of FIGS. 1-6 will include the features of the tray 100 that make the tray 100 suitable for accommodating these devices.

For example, in one embodiment the first compartment base member 107 includes a stair-stepped contour 115 suitable for accommodating a plurality of syringes at different heights. For example, a first step portion 116 of the stair-stepped contour 115 may be at a different height within the tray 100 than a second step portion 117 of the stair-stepped contour. In the illustrative embodiment of FIGS. 1-6, the first step portion 116—which is disposed farther from the first barrier 105 than the second step portion 117—is shallower than the second step portion 117. Said differently, the second step portion 117 is disposed at a greater depth within the tray 100 than the first step portion 116.

The stair-stepped contour 115 can be used as mnemonic device when multiple syringes are stored within the first compartment 101. For example, it may be intuitive that a syringe placed on a higher step portion may need to be used first. This intuition is further enforced when the higher step portion is disposed farther to the left in a left-to-right usage configuration. Thus, a user receives a mnemonic reminder to use a syringe disposed on the first step portion 116 prior to a syringe disposed on the second step portion 117, as it is both higher and farther to the left.

Where syringes are stowed in the first compartment 101, the first compartment base member 107 can further be configured for syringe ease of use. For example, in one embodiment the first compartment base member 107 is inclined relative to other compartment base members. In the illustrative embodiment of FIGS. 1-6, the second compartment base member 108 and third compartment base member 109 are substantially coplanar with each other. Further, the second compartment base member 108 and third compartment base member 109 are generally flat in these views, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that contours could be incorporated into one or both of these base members.

In this illustrative embodiment, however, the first compartment base member 107 is configured to be inclined relative to one or both of the second compartment base member 108 and third compartment base member 109. As such, the stair-stepped contour 115 forms a ramp upon which syringes may be placed so that the plunger of each syringe is predisposed to project upward and out of the tray 100. Said differently, the stair-stepped contour 115 is configured such that the first step portion 116 and the second step portion 117 are disposed in a non-parallel orientation relative to the second compartment base member 108. This configuration makes it easier for a medical services provider to grasp the syringes and remove them from the tray 100.

The first compartment base member 107 may include other features suitable for accommodating one or more syringes as well. In one embodiment, one or both of the first step portion 116 and second step portion 117 include recesses 118, 119 for accommodating a syringe flange. These recesses 118, 119 generally function to prevent the syringes

US 11,661,220 B2

7

from sliding lengthwise within the first compartment 101. Similarly, in one embodiment one or both of the first step portion 116 and the second step portion 117 include protrusions 120 that help to prevent the syringes from sliding laterally within the first compartment 101.

In one embodiment, one or both of the first barrier 105 and the second barrier 106 include openings disposed therein. In the illustrative embodiment shown in FIGS. 1-6, the first barrier 105 includes a first opening 121 between the first compartment 101 and the second compartment 102. Similarly, the second barrier 106 includes a second opening 122 between the second compartment 102 and the third compartment 103. Each of these openings has an opening depth associated therewith. Similarly, each opening has an opening width associated therewith. In the illustrative embodiment of FIGS. 1-6, the first opening 121 is bounded by a first opening base member 129 and two inclined first opening side members 127, 128, while the second opening 122 is bounded by a second opening base member 131, an inclined second opening side member 130, and the perimeter wall 110.

While the opening depths can be the same, in one embodiment the opening depths are different. For example, in the illustrative embodiments of FIGS. 1-6, the first opening 121 has a first opening depth 123 that is less than the second opening depth 124 of the second opening 122. Similarly, in one embodiment the opening widths are different. For example, in the illustrative embodiments of FIGS. 1-6, the first opening 121 has a first opening width 125 that is less than the second opening width 126 of the second opening 122. Such a disparity in opening depths and widths, as well as the inclusion of inclined opening side members, provides an advantage in some applications.

For instance, in many catheter procedures a pair of syringes—such as syringes having a one-half inch diameter—fits easily into the first compartment 101 when the tray 100 is made with the illustrative dimensions set forth above. However, some procedures require one or more of the syringes to be larger. For example, some syringes are larger in diameter. These larger syringes are capable of nesting within the first opening 121 and second opening 122. The inclined opening side members prevent the syringe from moving lengthwise, while the disparate opening heights prevent the plunger of the syringe to the medical services provider for easy removal from the tray 100.

The stair-stepped contour 115, working in tandem with the first opening 121, gives the tray additional advantages over prior art catheter containers. For instance, when the first compartment 101 has a first compartment base member 107 configured with a stair-stepped contour 115, the first compartment 101 can be used as a lubricant applicator for the catheter.

Specifically, the medical services provider may dispense the lubricating jelly along the second step portion 117. As the second step portion 117 is lower in the tray 100 than the first step portion 116, the second step portion 117 serves as a channel in which the lubricating jelly may spread. A medical services provider may then pass the catheter through the first opening 121, through the channel formed by the second step portion 117, i.e., along the second step portion 117 through the dispensed lubricating jelly, and out the top of the tray 100 to the patient. This feature of the tray 100 greatly eases the application of lubricating jelly to the catheter when compared to prior art solutions. In one embodiment, the tray 100 is packaged with printed instructions showing the medical services provider how to apply

8

lubricating jelly in this manner. The printed instructions will be described in more detail below with respect to FIGS. 12-23.

It will be clear to those of ordinary skill in the art having the benefit of this disclosure that alternative methods may be used to apply the lubricating jelly as well. For example, in another embodiment, the lubricating jelly is dispensed directly onto the catheter tubing while the tubing is in or above the first compartment 101. Excess lubricant falling from the catheter tubing can then collect, and be retained, in the second step portion 117.

This particular feature highlights another advantage of the “compartmentalized” structure of various embodiments of the invention. As the tray 100 includes multiple compartments, various tasks associated with a catheterization procedure can be completed while keeping the catheter within the tray 100. The ability to keep the catheter in the tray 100 reduces the risk that the catheter or corresponding devices will be contaminated with bacteria or microbes on other objects within the procedure room. For example, when the first compartment 101 is used to apply lubricating jelly to the catheter, the lubricating jelly can be applied while the catheter is contained within the tray 100, thereby reducing the risk that the catheter will become contaminated. This correspondingly reduces the risk of infection for the patient receiving the catheter.

Prior art systems, for example such as those in which the catheterization procedure components are shipped in separate containers, may contribute to substandard techniques in that the catheter can become contaminated when moving it from its shipping container. Consequently, the patient can be at an elevated risk of infection as the catheter is moved from one tray to another. Embodiments of the present invention solve this problem by providing a single level tray 100 with compartments. Further, in one embodiment the first compartment 101 includes the first opening 121 so the catheter can stay in place during and after lubrication. By having easy access to the components disposed in the single level tray 100, the medical services provider can more easily prepare and use the components within the tray 100. This helps to minimize the risk of contaminating the patient or the sterile field during the procedure.

In one embodiment, the second step portion 117 is configured to be inclined at a shallower angle than the first step portion 116 in at least a portion opposite the recess 119 from the first opening 121. When configured in such a fashion, the second step portion 117 includes a “cutdown” so that the catheter can stay within the channel both during and after lubrication.

Additionally, the catheter can be placed in both the first opening 121 and second opening 122 during lubrication. When positioned in this configuration, the second opening 122 helps to align the catheter with the first opening for easy passage through the lubrication channel formed by the second step portion 117.

The tray 100 of FIGS. 1-6 includes additional advantages over prior art catheter packaging as well. For example, in one embodiment, instructions 132 or other graphical indicia can be printed, placed upon, or molded into the horizontal flange 111. In one embodiment, compartment designations can be placed above each compartment to ensure the medical services provider uses the correct device or material at the correct time. In another embodiment, expiratory dates for materials or devices disposed within the tray 100 may be placed on the horizontal flange 111. It will be obvious to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. Any number

US 11,661,220 B2

9

of various text or picture combinations can be printed on, placed upon, or molded into various parts of the tray. For instance, graphical indicia can be applied to the compartment base members in addition to the horizontal flange 111. Note that the horizontal flanges, in one embodiment, can terminate in downwardly protruding vertical flanges for increased stability during the printing process.

Another advantage of the tray 100 is that its compartmentalized configuration helps to reduce the risk of contaminating a patient or compromising the sterile nature of the components stored in the tray 100. Since both the catheter assembly and medical devices corresponding to catheter use are stored within the same tray 100, the risk of cross-contamination between sterile work areas and non-sterile spaces is minimized. Further, by having the catheter assembly and the devices corresponding to catheter use stowed in a one-level tray rather than a multi-level, stacked configuration, the medical services provider can more easily prepare and use the catheter and corresponding devices disposed within the tray 100.

Turning now to FIGS. 7-9, illustrated therein is a tray having a catheter assembly 700, syringes 701,702, and a specimen container 703 stored therein as a catheter packaging system in accordance with one embodiment of the invention. As with FIGS. 1-6, FIGS. 7-9 will be referred to collectively with like reference numerals referring to identical or functionally similar elements throughout the separate views. FIG. 7 illustrates a top, front, right perspective view of the catheter packaging system, while FIG. 8 illustrates a top plan view of the catheter packaging system. FIG. 9 illustrates a transparent, front elevation view of the catheter packaging system.

The illustrative catheter packaging system of FIGS. 7-9 includes a tray 100 having a first compartment 101, a second compartment 102, and a third compartment 103. In this illustrative embodiment, the first compartment 101 is configured to accommodate syringes 701,702. The second compartment 102 is configured to accommodate a coiled medical device, such as catheter assembly 700. The third compartment 103 is configured to accommodate the specimen container 703. The third compartment 103 can accommodate other materials as well, including skin sanitizers and cleansing liquids, solutions, or gels. As mentioned above, additional devices corresponding to catheter use, including towels, drapes, rubber gloves, and so forth, can be disposed in the tray 100 as well. As an illustration of this flexibility, a towel 704 is disposed beneath the catheter assembly 700.

As noted above, in one embodiment the flange 111 can include instructions 770 or other graphical indicia. As also noted above, the implements disposed in the various compartments 101,102,103 can have implements therein arranged in accordance with use. In one embodiment, shown illustratively in FIG. 7, the instructions 770 can be coordinated with this arrangement, indicating that components disposed in the first compartment 101 should be used first, components disposed in the second compartment 102 should be used next, and so forth. To assist the user in understanding workflow, arrows 771 or other directional elements can be included on the flange 111 as well.

As illustrated in FIGS. 1-6, each compartment of the tray 100 includes a compartment base member. Further, each compartment is separated by a barrier having an opening therein. A first barrier 105 having a first opening 121 therein separates the first compartment 101 from the second compartment 102. Similarly, a second barrier 106 having a second opening 122 therein separates the second compartment 102 from the third compartment.

10

Syringes 701,702 are disposed in the first compartment, with one syringe 701 being supported at a different elevation within the tray than the other syringe 702. The different elevations can be relative to each syringe 701,702, or to other components of the tray 100, such as the second compartment base member 108. Said differently, one syringe 701 is supported by the first compartment base member 107 at a shallower depth within the tray 100 than the depth of the second compartment base member 108. Further, where the first compartment base member 107 is inclined relative to other base members, one or both syringes 701,702 will be supported in a non-parallel configuration relative to the second compartment base member 108. This is most readily seen in FIG. 9.

As noted above, some medical procedures will call for more materials than can be accommodated by a syringe capable of fitting within the first compartment 101. For such procedures, the tray 100 can be packed with larger syringes. A large syringe (not shown) can be supported laterally within the tray 100 when it is placed across the tray 100 such that it lies within both the first opening 121 of the first barrier 105 and the second opening 122 of the second barrier 106. Such a syringe will pass across the top of the catheter assembly 700, but will be held in place by the side members of each opening.

Turning now to FIG. 10, illustrated therein is an exploded view of the tray 100 having the catheter assembly 700, a pair of syringes 701,702, and a specimen container 703 disposed therein. While only a specimen container 703 is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks. Other devices could also be inserted into the tray 100 in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag, which is a dated and/or time stamped label that is secured to the catheter tubing once the catheter is inserted, can be inserted into the second compartment 102. Also, note that the pair of syringes 701,702 can be configured as shown in FIG. 10, or alternatively can be both inserted in the first compartment, as described above. In the configuration of FIG. 10, rather than having both syringes 701,702 disposed within the first compartment 101, one syringe 702 is disposed laterally in the first opening 121 and the second opening 122 of the first barrier 105 and second barrier 106, respectively. This configuration is illustrative only.

Once the necessary components are disposed within the tray 100, the tray can be sealed with a wrap 1000 to keep the internal components sterile. The wrap 1000 can be any of a number of types of material. In one embodiment, the wrap 1000 comprises a Central Sterile Reprocessing (CSR) wrap that is used widely by medical professionals in hospitals, ambulatory surgical centers, and the like during medical procedures. While a CSR wrap is one example of a wrap that can be used, it will be clear to those of ordinary skill in the art that other wraps, such as plastic, cotton, linen, paper, or combinations thereof, can be substituted without departing from the spirit and scope of the invention.

Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. 10, the CSR wrap 1000 is folded about the tray 100 for sealing, and can be correspondingly unfolded to reveal the tray 100. Once unfolded, the CSR wrap 1000 can then be used in the catheter insertion process. For example, an unfolded CSR wrap 1000 can be used to provide a sterile field in which the tray 100 sits for

US 11,661,220 B2

11

unloading and subsequent use. This process will be explained in more detail in the discussion of FIGS. 22-30 below.

Printed instructions **1001** can then be attached to, disposed upon, or disposed within the tray **100**. In one embodiment, the printed instructions **1001** include a health care services portion and a patient portion, as will be shown in FIGS. 12-13 below. The health care services portion can include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly **700** disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

The patient portion can include helpful suggestions or instructions for the patient. The patient portion can be detachably coupled to the health care services portion, such as by a perforated line that is easily torn to separate the patient portion from the health care services portion. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly **700**. In one embodiment, the health care services portion may include an instruction for the health care services provider to detach the patient portion from the health care services portion and instructions to discuss the patient portion with the patient.

The health care services portion can tell the medical services provider how to perform a standard catheterization procedure. For instance, in one embodiment, the tray **100** is equipped with an adhesive label that can be used to identify the patient or specimen in the specimen container **703**. Further, a label can be included to mark or otherwise identify the material in the fluid bag attached to the catheter. Such labels can include pre-printed fields, such as date, time and name. Further the printed instructions **1001** can notify the medical services provider that the devices disposed within the tray **100** are ordered corresponding to use during the catheterization procedure.

In another embodiment, the printed instructions **1001** can inform the medical services provider of special instructions. For instance, in one embodiment the printed instructions **1001** can inform the medical services provider not to leave a catheter in a patient for more than forty-eight hours without a physician's approval. Where the printed instructions **1001** include such information, the labels included in the tray **100** may have pre-printed fields for the time of insertion that can be filled in by the medical services provider performing the catheterization procedure.

Once the printed instructions **1001** have been affixed to, or placed with, within, or atop the tray **100**, the assembly can be sealed in a sterile wrap **1002** such as a thermally sealed bag. The thermally sealed bag can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the bag. Inclusion of a sterile wrap **1002** not only keeps the contents within the bag sterile, but also allows the instructions to be included with the tray assembly, yet outside the CSR wrap **1000**.

12

In one embodiment the printed instructions **1001** are disposed atop the CSR wrap **1000** such that the health care services portion of the printed instructions **1001** is disposed on the top of the printed instructions **1001**, with the patient portion being disposed adjacent to the CSR wrap **1000**, such as when the printed instructions **1001** are configured as an accordion-style folded instruction pamphlet. While the printed instructions **1001** of one embodiment are configured as a folded, printed, separate article disposed atop the CSR wrap **1000**, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, in one embodiment the sterile wrap **1002** can be optional. In one embodiment, rather than including separate printed instructions **1001**, the instructions for use can be printed on the CSR wrap **1000** as well.

Additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag **1003** can be affixed to the sterile wrap **1002**. In another embodiment the instruction tag may be adhered to an outer packaging, that encloses the tray, the sterile wrap material or both. For example, in one embodiment the instruction tag **1003** can include information regarding whether a catheter procedure is needed. Text **1004** such as "Is there a valid clinical reason?" may be included under an instruction to "Stop" that includes the following information:

Before inserting the Foley catheter, at least one of the following conditions should exist:

- Acute urinary retention or obstruction
- Precise measurement of urinary output needed
- Select surgical procedures
- Open sacral or perineal wounds in incontinent patient
- Prolonged immobilization
- End of life care

Further, checklist text **1005** may be included, such as "Checklist for Foley Catheter Insertion" included under the word "Check" that includes the following information:

- Check Each Box Upon Completion:
- Obtain order from physician/provider
- Document clinical reason for insertion
- Explain procedure to patient
- Use smallest catheter possible
- Perform hand hygiene
- Follow aseptic technique

Additional information may also be included, such as a fillable form **1006** that provides fields for the date and time of insertion of the catheter to be recorded, the name of the health care services provider, and the signature of the health care services provider. The above text **1004** for the instruction tag **1003** is illustrative only, and may be customized as desired by the manufacturer.

Turning now to FIG. 11, illustrated therein is a method **1100** for manufacturing a packaged catheter assembly in accordance with embodiments of the invention. At step **1101**, the manufacturer provides a tray (**100**) having at least a first compartment (**101**) for accommodating one or more syringes (**701,702**) and a second compartment (**102**) for accommodating a flexible medical device, such as a catheter assembly (**700**). As noted above, in one embodiment the first compartment (**101**) will have a first compartment base member (**107**) having an inclined, stair-stepped contour (**115**). The first compartment (**101**) and second compartment (**102**) can be separated by a first barrier (**105**) having an opening (**121**) therein.

Once the tray (**100**) is procured, the manufacturer can dispose at least one syringe (**701**) in the first compartment (**101**) at step **1102**. Optionally, at step **1103**, the manufac-

US 11,661,220 B2

13

turer may include additional components with the tray (100). For example, a catheter securement device, a Foley insert tag, or other complementary components may be included at this step 1103.

In one embodiment, as determined at decision 1105, a second syringe (702) will be disposed in the first compartment (101) at step 1106. In another embodiment, the second syringe (702) will be disposed laterally within the first opening (121) and, where present, a second opening (122) at step 1107.

At step 1104, the manufacturer will place the catheter assembly (700) in the second compartment (102). Other components may be disposed in the tray (100) as well, including a specimen container (703) that is disposed in a third compartment (103) at step 1108. Further, other devices may be included, such as towels, drapes, printed instructions, one or more antiseptic packets, and so forth. These other devices can be disposed in various compartments within the tray (100).

At step 1109, the tray (100) is sealed. This can be accomplished by folding a CSR wrap about the tray (100). In such an embodiment, the CSR wrap can be used during the catheter insertion procedure as well. At optional step 1110, the manufacturer can enclose printed instructions (1001). In one embodiment, the printed instructions (1001) will direct a user to discharge contents of at least one syringe into the first compartment (101) and to pass at least a portion of the catheter assembly (700) through the opening and into the contents to lubricate the catheter.

At step 1111, the manufacturer can place a sterile wrap about the tray (100) and the printed instructions (1001), where included. A sticker or other sealing device can be applied that indicates the contents to be sterile as well. At step 1112, the completed assembly can be shipped to a medical services provider.

Turning now to FIGS. 22-30, illustrated therein is a method of packaging a catheter assembly and corresponding tray in accordance with embodiments of the invention. FIGS. 22-30 illustrate one exemplary method graphically, which each figure representing one or more steps of the method, as the illustrations serve to better explain these steps than would a flow chart or other diagram. While FIGS. 22-30 illustrate one method of packaging a tray and catheter assembly, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that other methods can be used as well. Further, in creating this article of manufacture, i.e., the packaged catheter assembly, the steps of FIGS. 22-30 may be either manual or automated. A person can execute the steps to create the article of manufacture in one embodiment. Alternatively, industrial machinery, equipment, and robotics can be designed and programmed to execute the steps with the assistance of one or more processors and executable instructions stored in memory.

Beginning with FIG. 22, in this step, a tray 100 is provided. The tray includes at least one compartment, such as the first compartment 101 that is configured for receiving the catheter assembly 700. As described above, the tray 100 can include additional compartments as well, such as those for receiving syringes, specimen jars, and so forth.

At this step, the catheter assembly 700 is placed within the first compartment 101 as previously described. The tray is then placed upon one or more layers of wrap material 2200. In one embodiment, the wrap material 2200 can be CSR wrap. For example, in the illustrative embodiment of FIG. 22, the wrap material 2200 comprises a white layer of CSR wrap measuring 24 inches square. As previously noted, other materials can be used as well, including plastic materials,

14

cotton materials, paper materials, synthetic materials and so forth. The wrap material 2200 can be of different shapes and sizes as well.

While the tray 100 can be sealed with a simple layer of plastic adhered to the top of the tray 100, providing the wrap material 2200 can be advantageous in many applications. For example, as will be explained below with respect to FIGS. 31-33, when the wrap material 2200 is a medically usable material, such as CSR wrap, a medical services provider may unfold the wrap about the tray 100 to create a sterile field for the catheterization procedure. For this reason, one or more layers of wrap material 2200 are simply folded about the tray 100 in this illustrative embodiment.

Note that for reference and ease of explanation, the tray 100 will be described as having four sides: a first side 2201, a second side 2202, a third side 2203, and a fourth side 2204. As these sides will not be visible in every view, due to the folding of the wrap material 2200 about the tray 100, they are initially noted here. Note that four sides are used because the illustrative tray 100 is rectangular in shape. Were the tray a triangle, there would be three sides. Were the tray oval or circular, there would be an infinite number of sides.

Turning now to FIG. 22, at this step a first portion 2301 of the one or more layers of wrap material 2200 is folded about a first side (2201) of the tray 100. In this illustrative embodiment, the tray 100 is oriented at a rotation of approximately forty-five degrees relative to the one or more layers of wrap material 2200, with both the wrap material 2200 and the tray 100 being rectangular in shape. As such, the first portion 2301 comprises a first corner of the wrap material 2200. It will be clear to those of ordinary skill in the art having the benefit of this disclosure, however, that embodiments of the invention are not so limited. For example, the wrap material 2200 can be configured as a circle or oval. Executing the step shown in FIG. 22, a first portion of that material could be folded about a first side of the tray 100 in similar fashion.

Turning to FIG. 23, illustrated therein is an optional step that can be included in the method of packaging the catheter assembly. As noted above, in one embodiment the one or more layers of wrap material 2200 can be unfolded to create a sterile field about the tray 100. A patient can be placed atop this sterile field for the catheterization procedure. Even if the surface below the wrap material 2200 is also sterile, the use of the wrap material 2200 as a foundation for the procedure further ensures that the sterile field will not be breached.

Turning now to FIG. 24, to help ensure that the health care provider does not inadvertently breach the sterile field, in one embodiment a package of liquid hand sanitizer 2401 or other cleanser and/or a package of rubber gloves 2402 may be included. Alternatively, other medical implements such as alcohol wipes or other materials could be enclosed as well. In such an embodiment, upon opening the packaged catheter assembly, the health care services provider may—before ever touching the catheter assembly or tray contents—apply the liquid hand sanitizer 2401 to their hands and dawn rubber gloves. The inclusion of these accessories in the packaging eliminates the need for the health care services provider to have to leave the sterile field to wash their hands, obtain gloves, and so forth.

In the illustrative embodiment of FIG. 23, the package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are simply placed atop the first portion 2301 of the one or more layers of wrap material 2200. As will be shown below, they will be held in place by other portions of the one or more layers of wrap material 2200 by way of subsequent folding steps. Other methods of holding them in place,

US 11,661,220 B2

15

including light adhesives or the design of pockets in the one or more layers of wrap material 2200 may also be used. The sanitizer 2401 and gloves 2402 are shown placed atop the first portion 2301, but may be alternatively placed atop, and therefore outside of the sterile field, other layers of the wrap as well, (for example, 2501, 2601, 2801 or the like).

Turning now to FIG. 25, at this step a second portion 2501 of the one or more layers of wrap material 2200 is folded about a second side (2202) of the tray 100. Where the optional package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are included, the second portion 2501 of the one or more layers of wrap material 2200 may be folded so as to cover or partially cover these items.

Turning now to FIG. 26, at this step of the method a third portion 2601 of the one or more layers of wrap material 2200 is folded about a second side (2203) of the tray 100. Where the optional package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are included, the third portion 2601 of the one or more layers of wrap material 2200 may be folded so as to cover or partially cover these items.

Turning now to FIG. 27, illustrated therein is another optional step of the method of packaging the catheter assembly and tray. In many catheterization procedures, a first layer of material will be placed under the patient, while a second layer of material is placed atop the patient. For such applications, the packaged catheter assembly can include an additional layer of wrap material 2701. In the illustrative embodiment of FIG. 25, the additional layer of wrap material 2701 comprises a folded layer of CSR wrap measuring 17 by 17.5 inches. The additional layer of wrap material 2701 in this illustrative embodiment is folded as a 4 by 2 matrix.

The one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be the same type of material. Alternatively, the one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be different. In one embodiment, for example, the additional layer of wrap material 2701 can be a fenestrated wrap with one or more pre-formed openings suited to the catheterization procedure.

In one embodiment, the additional layer of wrap material 2701 is configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of wrap material 2701 is a different color than the one or more layers of wrap material 2200. The one or more layers of wrap material 2200 can be white, for instance, while the additional layer of wrap material 2701 can be light blue or light green. Other color combinations can equally be used.

As with the package of liquid hand sanitizer 2401 and package of rubber gloves 2402, in one embodiment the additional layer of wrap material 2701 can be placed atop portions of the one or more layers of wrap material 2200. In such an embodiment, the additional layer of wrap material 2701 can be held in place by way of subsequent folding steps, as the additional layer of wrap material 2701 is disposed along other folded portions of the one or more layers of wrap material 2200 prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (2204) of the tray (100).

As will be shown below, medical procedure kits configured in accordance with embodiments of the invention can include printed instructions. The printed instructions can include a patient portion and a health care services provider portion. The health care services provider portion can include information such as how to use the medical procedure kit, what is included therein, checklists, and so forth.

16

The patient portion can include helpful information for the patient, such as information about the procedure, questions to ask, and post procedure care suggestions. These two portions can be detachably coupled together. Alternatively, they can be separate.

In one embodiment of the invention where the health care services portion of the printed instructions are physically separated from the patient portion, it can be advantageous to stage the various portions at different locations within the assembled medical procedure kit. One advantage offered by embodiments of the invention is that the medical devices and implements can be staged within the kit in accordance with an order of use. Accordingly, the health care services provider can draw out each device in order of use.

Turning now briefly to FIG. 34, illustrated therein is an alternate embodiment of the stage shown in FIG. 27. The embodiment of FIG. 34 is well suited to situations in which the health care services portion is physically separated from the patient portion.

In FIG. 34, another optional step corresponding to a method of packaging a medical procedure kit is shown. As with FIG. 27, the medical procedure kit of FIG. 34 illustrates a packaged catheter assembly. Also as with FIG. 27, the packaged catheter assembly can include an additional layer of material 2701, which may be a patient drape, under-buttocks drape, or a combination thereof disposed within one or more layers of wrap material 2200. As noted above, the additional layer of material 2701 can be configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of material 2701 is a different color than the one or more layers of wrap material 2200.

The package of liquid hand sanitizer 2401 and package of rubber gloves 2402, optionally the additional layer of material 2701, and the separated health care services portion 3401 of the printed instructions can be placed atop portions of the one or more layers of wrap material 2200. In such an embodiment, the package of liquid hand sanitizer 2401, the rubber gloves 2402, the additional layer of material 2701, and the separated health care services portion 3401 can be held in place by way of subsequent folding steps, as they are disposed along other folded portions of the one or more layers of wrap material 2200 prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (2204) of the tray (100). Accordingly, the health care services provider will be readily able to access these devices after unfolding a single fold of the one or more layers of wrap material 2200.

Turning now to FIG. 28, the tray (100) is enclosed in the one or more layers of wrap material 2200 by folding a fourth portion 2801 of the one or more layers of wrap material 2200 about a fourth side (2204) of the tray (100) and then tucking at least one of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the one or more layers of wrap material 2200 beneath at least another of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the layer of wrap material 2200. In the illustrative embodiment of FIG. 28, a part of the fourth portion 2801 is tucked beneath parts of each of the (2301), the second portion (2501), and the third portion (2601). This step of tucking encloses both the additional layer of wrap material 2701 and the package of liquid hand sanitizer (2401) and the package of gloves (2402) within the one or more layers of wrap material 2200.

Turning briefly to FIG. 35, illustrated therein is a variation of FIG. 28 in which the printed instructions include a health

US 11,661,220 B2

17

care services portion and a patient portion, wherein these portions are separate. In FIG. 35, as with FIG. 28, the tray (100) is enclosed in the one or more layers of wrap material 2200 by folding a fourth portion 2801 of the one or more layers of wrap material 2200 about a fourth side (2204) of the tray (100) and then tucking at least one of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the one or more layers of wrap material 2200 beneath at least another of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the layer of wrap material 2200. The separated health care services portion 3401 of the printed instructions is thus tucked within the fourth portion 2801.

The separated patient portion 3501 is then placed atop the fourth portion 2801. The health care services provider is therefore able to access the separated patient portion 3501 and deliver it to, and possibly discuss it with, a patient prior to unfolding the fourth portion 2801. The step of tucking shown in FIG. 34 encloses each of the additional layer of wrap material 2701, the separated health care services portion 3401, the package of liquid hand sanitizer (2401) and the package of gloves (2402) within the one or more layers of wrap material 2200, while leaving the patient portion 3501 outside the various folds of the one or more layers of wrap material 2200.

Turning now to FIG. 29, the packaged catheter assembly 2901 can be sealed in a bag 2902 as was described in FIG. 10. Prior to depositing the packaged catheter assembly 2901 into the bag 2902, optional printed instructions 1001 can be attached to or disposed upon the packaged catheter assembly 2901 as well. As with FIG. 10, the printed instructions 1001 can include a health care services portion and a patient portion as shown in FIGS. 12-13. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

Turning briefly to FIG. 36, illustrated therein is an alternative to FIG. 29, which is used when printed instructions including a health care services provider portion and a patient portion, each physically separate from the other, is included. In FIG. 36, the packaged catheter assembly 2901 having the tucked-in, separated health care services portion 3401 of the printed instructions is sealed in a packaging material. The packaging material of FIG. 36 is illustratively shown as a bag 2902.

Prior to depositing the packaged catheter assembly 2901 into the bag 2902, the separated patient portion 3501 of the optional printed instructions can be attached to or disposed upon the packaged catheter assembly 2901 as described in FIG. 35.

Once the printed instructions 1001 have been affixed to, or placed with or atop the packaged catheter assembly 2901, as in either FIG. 29 or 36, the assembly can be sealed in a sterile wrap such as a bag 2902, which may be thermally or otherwise sealed. The completed assembly 3001 is shown in FIGS. 30 and 37, where an outer packaging material is shown. In FIGS. 30 and 37, the outer packaging material is a thermally sealed bag 2902. It will be understood that this outer packaging is but one embodiment of the various packaging materials that can be used in accordance with embodiments of the invention. In FIGS. 30 and 37, the thermally sealed bag 2902 optionally includes a preformed opening 3002. For example, in one embodiment, the preformed opening 3002 can include one or more tabs that a health care services provider is instructed to pull to open the bag 2902. Inclusion of a sterile wrap not only keeps the contents within the bag sterile, but also allows the printed

18

instructions 1001 to be included with the tray assembly, yet outside the one or more layers of wrap material (2200).

Turning back to FIG. 29, in one embodiment the printed instructions 1001 are disposed atop the one or more layers of wrap material 2200 such that the health care services portion of the printed instructions 1001 is disposed on the top of the printed instructions 1001, with the patient portion being disposed adjacent to the one or more layers of wrap material 2200. As with FIG. 10, additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag 1003 can be affixed to the bag 2902.

Turning now to FIGS. 38 and 39, illustrated therein are steps of method of assembling yet another embodiment of medical procedure kit in accordance with embodiments of the invention. In FIGS. 38 and 39, the printed instructions are physically separated into a patient portion 3801 and a health care services provider portion 3802, as was the case in FIGS. 34-37. However, unlike FIGS. 34-37, the embodiment of FIGS. 38 and 39 has the health care services provider portion 3802 configured as an adhesive label with the checklist 1003 forming an extension thereof. Further, as will be shown in more detail in FIG. 40, the health care services provider portion 3802 has a picture of the contents of the medical procedure kit on the top, and has a peelable flap 3803 that may be opened to reveal instructions and other indicia therein.

Another difference in the embodiment of FIGS. 38 and 39 involves the patient portion 3801. While some embodiments provide a patient portion that is very straight-forward, informational, and clinical in nature, in the embodiment of FIGS. 38 and 39, the patient portion 3801 is configured as a greeting card. Experimental testing has shown that when the patient portion is configured as an instruction or informational sheet, it is less likely that the patient portion will be delivered to the patient. However, by configuring the patient portion 3801 as a greeting card, such as with a pleasant picture of flowers or similar objects on the front and stylized text providing the information therein, it is more likely to be given to the patient. The patient portion 3801 will be described in more detail below.

Beginning with FIG. 38, illustrated therein is an exploded view of a tray 100 suitable for use in a medical procedure kit. The tray 100 has the catheter assembly 700, a pair of syringes 701,702, and a specimen container 703 disposed therein. While only a specimen container 703 is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks. Other devices could also be inserted into the tray 100 in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag can be inserted into the second compartment 102. Also, note that the pair of syringes 701,702 can be configured as shown in FIG. 38, or alternatively can be both inserted in the first compartment, as described above. In the configuration of FIG. 38, rather than having both syringes 701,702 disposed within the first compartment 101, one syringe 702 is disposed laterally in the first opening 121 and the second opening 122 of the first barrier 105 and second barrier 106, respectively. This configuration is illustrative only.

Once the necessary components are disposed within the tray 100, the tray can be enclosed with a wrap 1000. The wrap 1000 can be one or more layers in number, and further can be any of a number of types of material. In one embodiment, the wrap 1000 comprises a CSR wrap.

US 11,661,220 B2

19

Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. 38, the CSR wrap 1000 is folded about the tray 100 for sealing, and can be correspondingly unfolded to reveal the tray 100 and other implements. Once unfolded, the CSR wrap 1000 can then be used in the catheter insertion process. For example, an unfolded CSR wrap 1000 can be used to provide a sterile field in which the tray 100 sits for unloading and subsequent use. This process is explained in more detail in the discussion of FIGS. 22-30.

Printed instructions can then be attached to, disposed upon, or disposed within the tray 100. In the illustrative embodiment of FIG. 38, the printed instructions are configured as a physically separate health care services portion 3802 and a patient portion 3801, as will be shown in more detail in FIGS. 40-41 below. The health care services portion 3802 can include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly 700 disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

In the embodiment of FIG. 38, the health care services portion 3802 is configured with a checklist 1003 extending therefrom. Further, the health care services portion 3802 includes, in one embodiment, a photograph of the contents disposed within the medical procedure kit. When viewing the health care services portion 3802 from the top, the health care services provider is able to easily inventory what contents are disposed therein.

In one embodiment, the health care services portion 3802 includes a peelable flap 3803. By pulling back the peelable flap 3803, the health care services portion 3802 opens to reveal instructions and other information therein. For example, in one embodiment, the interior of the health care services portion 3802 can include one or more of the panels shown in FIGS. 15-19. In one embodiment, the health care services portion 3802 may include an instruction for the health care services provider to give the patient portion 3801 to the patient, and in one embodiment, instructions to discuss the patient portion 3801 with the patient.

The patient portion 3801 can include helpful suggestions or instructions for the patient. The patient portion 3801 can be configured as a greeting card to make the information more pleasantly received by a patient. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly 700.

In the embodiment of FIG. 38, the patient portion 3801 is disposed within the packaging 3804, while the health care provider portion 3803 is affixed to the outside of the packaging 3804. As with FIG. 34, the medical procedure kit of FIG. 38 can include an additional layer of wrap material 2701 disposed within one or more layers of wrap material 2200. As noted above, the additional layer of wrap material 2701 can be configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of wrap material 2701 is a different color than the one or more layers of wrap material 2200.

20

The package of liquid hand sanitizer and package of rubber gloves described above (not shown in FIG. 38 for simplicity) can then be placed under the additional layer of wrap material 2701. The patient portion 3801 can be placed atop the additional layer of wrap material 2701. In such an embodiment, the package of liquid hand sanitizer (where used), the rubber gloves (where used), the additional layer of wrap material 2701, and the patient portion 3801 can be held in place by way of a final folding step 3805. Accordingly, they will be held in place by a folded portion 3806. The health care services provider will be readily able to access these implements after unfolding the folded portion 3806 shown in FIG. 38.

The health care services portion 3802 can be affixed to the packaging 3804. The packaging 3804 can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the packaging 3804.

Turning now to FIG. 39, illustrated therein is the medical procedure kit 3901 of FIG. 38 having the patient portion 3802 tucked into the one or more layers of wrap 2200. The health care services portion 3802 is affixed to the packaging 3804. The packaging 3804 of FIG. 39 is illustratively shown as a thermally or adhesively sealed bag.

Turning now to FIGS. 12-13, illustrated therein is one embodiment of the printed instructions 1001 in accordance with embodiments of the invention. The printed instructions 1001 can be configured as an instruction manual suitable for inclusion with a tray (100) as described above. FIG. 12 illustrates a view of a first side of the instruction manual, while FIG. 13 illustrates a view of a second side of the instruction manual.

In one embodiment, the printed instructions 1001 are configured as a two-portion instruction manual having a health care services portion 1201 and a patient portion 1202. In the illustrative embodiment of FIGS. 12-13, the patient portion 1202 is detachably coupled to the health care services portion 1201, and is thus separated from the health care services portion 1201, by a perforation 1203. For example, where the printed instructions 1001 are configured as a printed material on a paper-based stock, the perforation 1203 can be a perforated line running along a dimension of the printed instructions 1001 such that the printed instructions 1001 can be easily torn along the perforation 1203 to separate the patient portion 1202 from the health care services portion 1201. Note that the embodiment of FIGS. 12 and 13 is but one illustrative embodiment of the invention. The patient portion 1202 need not be detachably coupled to the health care services portion 1201. As will be shown in FIGS. 27-34 below, the patient portion 1202 may be physically separate from the health care services portion 1201 as well. In the separated configuration, the health care services portion 1201 and patient portion 1202 can be disposed at different locations within a medical procedure kit.

In one embodiment, the printed instructions 1001 are configured as a plurality of panels 1204, 1205, 1206, 1301, 1302, 1303. As will be shown in FIG. 20, in one embodiment the printed instructions 1001 can be configured as an instruction manual that is formed with an accordion-style fold, with each of the panels 1204, 1205, 1206, 1301, 1302, 1303 forming a page of the instruction manual. In the illustrative embodiment of FIGS. 12-13, panels 1204, 1205 and panels 1301, 1302 form the health care services portion 1201, while panels 1206, 1303 form the patient portion. Panels 1206, 1303 are separated from panels 1204, 1205 and panels 1301,

1302 by the perforation 1203 such that the patient portion 1202 is tearably separable from the health care services portion 1201.

In one embodiment, the health care services portion 1201 includes instructions 1304 for using the catheter assembly and other corresponding medical devices disposed within the accompanying tray. The instructions 1304 can include text and/or figures or illustrations showing how to use the catheter assembly and corresponding medical devices on the patient, as well as instructions on preparation, taking samples, preventing infection, and so forth. The instructions 1304, in one embodiment, also include an instruction to detach the patient portion 1202, give the patient portion 1202 to the patient, as well as an instruction to discuss the information disposed on the patient portion 1202 with the patient.

Similarly, the patient portion 1202 may also include instructions 1305 and/or helpful suggestions for the patient who is undergoing the catheterization procedure. For instance, this information can include any one or more of the following: a description of what a catheter is, what the patient should know about the catheter, how to reduce the chance of getting an infection from the catheterization procedure, what infections commonly associated with catheterization procedures typically are, the symptoms associated with infections commonly associated with catheterization procedures, and information about using the catheter at home. Additionally, the patient portion 1202 may include custom information as well. For example, in one embodiment the patient portion 1202 includes an informational section configured such that the health care service provider's name and contact information can be written thereon. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, additional types of health care service instructions or patient instructions or suggestions can also be included.

Turning now to FIGS. 14-19, illustrated therein are exemplary panels 1204, 1205, 1206, 1301, 1302, 1303. These panels 1204, 1205, 1206, 1301, 1302, 1303 are intended to illustrate exemplary instructions for the health care services portion (1201) and patient portion (1202) of an illustrative instruction manual for a catheter assembly and corresponding medical devices included with an accompanying tray (100). It will be clear that these panels 1204, 1205, 1206, 1301, 1302, 1303 and the information printed thereon can be varied in any number of ways without departing from the spirit and scope of the invention as described herein and recited in the following claims. For example, the number of panels can be varied. Additionally, the information printed thereon can be condensed, expanded, or altered without departing from the spirit and scope of the invention. Also, the exemplary information may be moved from the panels shown to other panels, as a particular application may warrant.

Beginning with FIG. 14, illustrated therein is one exemplary panel 1204. In one embodiment, panel 1204 will be configured such that when the catheter package assembly within which the instruction manual is disposed is initially opened, panel 1204 will be readily viewable. For example, where the catheter package assembly is assembled as shown in FIG. 10 above, once the sterile wrap (1002) is removed, the panel 1204 will be viewable prior to removal of the CSR wrap (1000).

Panel 1204 can include general information about the catheter assembly and corresponding medical devices disposed within the tray. For example, this information can include part number information 1401, trade name informa-

tion 1402, and manufacturer information 1403. A diagram 1404 of the contents of the package assembly may be included as well. The illustrative diagram 1404 of FIG. 14 illustrates a tray 100 having a catheter assembly 700 and corresponding medical devices disposed therein. The corresponding medical devices of this illustrative embodiment include a pair of syringes 701, 702 and a specimen container 703. Additionally swab sticks 1408, a catheter securement device 1409, a Foley insert tag 1410, vinyl gloves 1411, a fenestrated drape 1412, an underbuttocks drape 1413, and a hand sanitizer 1414 solution or wipe are disposed within the tray 100.

In addition to a diagram 1404, panel 1204 can also include a written description 1407 of the elements included in the tray 100. Further, sterility information 1407 can be included. Panel 1204 can even include instructional material 1406 on how to use the instruction manual as well.

Turning now to FIG. 15, illustrated therein is one embodiment of panel 1301. As will be described below with respect to FIG. 20, in one embodiment the printed instructions (1001) are configured as an accordion-style folded instruction manual. In such a configuration, panel 1301 can be disposed on the back of panel 1204. Panel 1301 will therefore be visible upon a health care services provider opening the instruction manual.

Panel 1301 can include instructions for using the catheter assembly and the corresponding medical devices. As can be seen from this illustrative embodiment, panel 1301 can include instructions for setting up a clean work area. The instructions can include text, pictures, illustrations, or combinations of these.

In one embodiment, the instructions for setting up a clean work area include a hygiene performance step 1501, which may include instructions to wash hands, optionally put on gloves (which at this step can be non-sterile gloves), and so forth. The instructions may then include information on opening the remainder of the catheter package assembly. For instance, in FIG. 15 step 1502 indicates that the health care provider should remove the CSR wrap (1000), which in this case is folded about the tray (100). Note that in this illustrative embodiment, as the CSR wrap (1000) is folded about the tray (100), removal of the CSR wrap (1000) by unfolding creates a sterile field about the tray (100).

Step 1503 then instructs the health care provide to pick up the underbuttocks of the patient and to place the underbuttocks wrap beneath the patient. Step 1504 then instructs the health care provider to use the hand sanitizing solution provided with the catheter package assembly.

As with other panels shown in FIGS. 14-19, the various panels may include suggestions 1505 for preventing a catheter associated urinary tract infection. Some of this information is illustratively shown in FIG. 15. It will be understood that this information can be placed on one or more panels.

In addition to information for setting up a clean work area, in one embodiment panel 1301 includes instructions for preparing the catheter assembly (700) as well. For example, step 1506 instructs the health care services provider to don sterile gloves, as the hands were sanitized at step 1504. Step 1507 tells the health care services provider to place the fenestrated drape with a shiny side down on the patient without contaminating the sterile gloves donned at step 1506. Step 1508 instructs the health care services provider to test the balloon of the catheter assembly with the water-filled syringe stored in the first compartment. Step 1508 also instructs the health care services provider to leave the syringe connected to the catheter assembly.

US 11,661,220 B2

23

Step 1509 then provides instructions on using the first compartment of the tray as a lubricant application chamber as described above. Specifically, in this illustrative embodiment, step 1509 instructs the health care services provider to inject the lubricating jelly found in the second syringe of the first compartment into the first compartment. Step 1509 also instructs the health care services provider to pass the tip of the catheter through the first opening in the wall separating the first compartment and second compartment into the lubricating jelly, thereby lubricating the tip of the catheter.

Turning now to FIG. 16, illustrated therein is an exemplary embodiment of panel 1302. The instructions printed thereon continue to provide the health care services provider with information regarding use of the catheter assembly. For example, in one embodiment, this information includes instructions on inserting the catheter.

At step 1601, the instructions direct the health care services provider to tear open the swab stick package and to use the swab sticks to clean the patient from the top down. The instruction also notes that each swab stick is intended for one use only to properly maintain the sterile field. Step 1602 directs the health care services provider to initiate the catheterization process by inserting the catheter assembly into the patient. Steps 1603 and 1604 continue this process as shown in FIG. 16.

Step 1605 directs the health care services provider to secure the drainage bag to the catheter assembly. Step 1606 directs the health care services provider to clean up upon completion of the catheterization process. Step 1607 provides instructions on completing the label on the Foley insertion tag included with the catheter package assembly and attaching it to the tubing or drain bag attached to the catheter assembly.

At step 1608, the health care services provider is instructed to detach the patient portion (1202) from the health care services portion (1201) by tearing the two apart along the perforation (1203). Step 1609 further instructs the health care services provider to discuss the patient information printed upon the patient portion (1202) with the patient. Step 1609 instructs that documentation of the entire procedure should be completed.

Turning now to FIG. 17, illustrated therein is one embodiment of panel 1303, which represents a first side of the patient portion (1202). This panel 1303 includes information 1701 describing what a catheter is and why a catheter might be used. The panel 1303 also includes information 1702 describing what the patient should know regarding catheters and catheter use. For example, this information 1702 might notify the patient that the health care services provider should wash hands prior to inserting the catheter, and that it is acceptable to ask them to do so if they have not done so before the patient.

The panel 1303 also includes information 1703 regarding how the patient can reduce the chances of getting an infection. This information 1703 can include a statement that the patient should wash their hands prior to touching the catheter assembly. The information 1703 may also include a statement that the drainage bag should always be kept at a level beneath the patient's navel, and that the patient should inform a helper when the bag is more than half full.

Turning to FIG. 18, illustrated therein is one embodiment of panel 1206. In this illustrative embodiment, panel 1206 forms the second side of the patient portion (1202) of the instruction manual, and accordingly, includes additional information that a patient may wish to know when using a catheter assembly.

24

By way of example, information 1801 informs the patient as to what common infections associated with catheter use are and how they are contracted. Information 1802 provides symptoms of these common infections, such as fever, blood in the urine, burning or painful urination, or frequent or more urgent urination after catheter removal. Information 1803 informs the patient of what they should know prior to going home after a catheter procedure.

Information 1804 comprises an informational section configured such that a health care provider's name and contact information may be written thereon. This is helpful to the patient in the event that the symptoms recited in information 1802 should arise after the procedure, in that the patient has readily available access to the information required to contact a physician or other health care provider. An advantage of having this information 1804 on the patient portion (1202) when the patient portion (1202) is detachable is that the patient can take it with them upon completion of the procedure.

Turning now to FIG. 19, which is a portion of the health care services portion (1201), illustrated therein is one embodiment of panel 1205 that provides additional health services information. For example, information 1901 for emptying the drain bag and information 1902 describing how to obtain a urine sample can be included.

Turning now to FIG. 20, illustrated therein is one physical configuration in which the printed instructions 1001 can be delivered along with the catheter package assembly in accordance with embodiments of the invention. FIG. 20 is but one of many configurations, and embodiments of the invention are not to be limited in this respect, as FIG. 20 is illustrative only.

In FIG. 20, the printed instructions 1001 are configured as a tri-section, accordion style bi-folded panel. Three sections 2000, 2001, 2002 are folded in an accordion style, with two folds 2003, 2004 existing between the sections 2000, 2001, 2002. When the printed instructions 1001 are configured as shown in FIGS. 12-13, folding the printed instructions 1001 in this manner allows the health care services portion 1201 to be disposed atop the patient portion 1202. Further, when the printed instructions are disposed atop a CSR wrap (1000) as shown in FIG. 10, by disposing the patient portion 1202 adjacent to the CSR wrap (1000), the health care services provider removing the sterile wrap (1002) off of the catheter package assembly will be assured of seeing the health care services portion 1201 first.

Turning now to FIG. 40, illustrated therein is an alternate embodiment of printed instructions 4000 configured in accordance with embodiments of the invention. The printed instructions 4000 of FIG. 40 are suitable for use as the health care services portion (3802) of FIGS. 38-39, in that it can be configured as an adhesive label with a peelable flap 4001. Further, the illustrative embodiment includes a checklist 4002 as described above in FIG. 38.

In the embodiment of FIG. 40, the top cover of the printed instructions 4000 include a picture 4003 of the contents of the medical procedure kit. In one embodiment, the picture 4003 is a color photograph set on a black background to make visibility simple. Above the picture is a title bar 4004. In one embodiment, the title bar 4004 tells a health care services provider what type of medical procedure kit is disposed therein, and is white text on a blue background.

A flap indicator 4005 indicates that more information is located within the printed instructions 4000. The additional information, which can be one or more of the panels shown in FIGS. 15-19 above, can be accessed by the peelable flap

US 11,661,220 B2

25

4001. In one embodiment, the flap indicator is configured with black text on a yellow background.

The checklist **4002** can be configured as described above. In the embodiment of FIG. **40**, a red warning bar **4006** having white text thereon is disposed above a checklist section **4007** that is yellow, having black text and white check boxes in this illustrative embodiment.

Turning now to FIG. **41**, illustrated therein is one embodiment of a patient portion **3801** configured as a greeting card as was described with FIGS. **38-39**. The patient portion **3801** in this illustrative embodiment includes an inspirational phrase **4103** on the front cover, along with an aesthetically pleasing image **4101**. The aesthetically pleasing image **4101** of FIG. **41** is a vase of flowers, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other aesthetically pleasing images include puppies, sunsets, mountain streams, and so forth. The bottom of the patient portion **3801** includes an identifier **4103** that tells the patient the purpose of the patient portion **3801**.

The interior of the patient portion **3801** can include text. For example, in one embodiment where the patient portion **3801** is to be included with a catheter assembly, the interior includes the following illustrative text:

Here is some simple information about foley catheterization:

1. What is a Urinary Catheter?

A thin flexible tube that drains urine from the bladder into a collection bag. The catheter helps:

When you can't urinate.

To measure how much urine you're producing.

During and after some surgeries or tests.

2. What should you know about your catheter?

Only a trained technician inserts a catheter when necessary, and it is removed as soon as possible.

Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter.

If your caregivers don't clean their hands, politely ask them to.

Do not disconnect the catheter yourself.

Inquire every day whether you still need the catheter.

3. What is 'catheter-associated' urinary tract infection (CAUTI)?

If a catheter introduces 'outside' germs into your urinary tract, they can cause an infection. If a UTI is acquired, you may experience:

Sudden fever and/or bloody urine.

Burning or painful urination, or pain below the stomach.

Frequent, or more urgent, urinating after catheter is removed.

Tell your provider right away. An antibiotic may be needed.

4. Can you reduce your chances of an infection? Absolutely!

Wash your hands before and after touching your catheter.

Make sure the tube is secured to your leg. Never twist, or tug on it.

Always keep the collection bag below the level of your belly button.

Do not disconnect the catheter yourself.

Ask your doctor every day whether you still need the catheter.

The above information on the patient portion **3801** can be printed in multiple languages, such as in Spanish or in English. Where two languages are used, the back portion may be the same as the image shown in FIG. **41**, but with the inspirational phrase **4102** and identifier **4103** set forth in a

26

different language. Further, alternatives and variations of the information can be substituted for the example set forth above.

Turning now to FIG. **21**, illustrated therein is a method **2100** of using the printed instructions (**1001**) as described herein. At step **2101**, a health care services provider removes the sterile wrap (**1002**) disposed about the catheter package assembly. Where the catheter package assembly is configured as shown in FIG. **10**, removal of the sterile wrap (**1002**) will reveal the printed instructions (**1001**). Where the printed instructions (**1001**) are configured as described in FIG. **20**, with the patient portion (**1202**) disposed adjacent to the CSR wrap (**1000**), the health care services provider will see the health care services portion (**1201**) first.

At step **2102**, the health care services provider accesses the printed instructions (**1001**) and begins to read the panels, which in one embodiment are panels configured in accordance with those described in FIGS. **14-19** above.

At step **2103**, the health care services provider unfolds the outer CSR wrap (**1000**), which in one embodiment is then used to create a sterile field about the tray (**100**). At step **2104**, the health care services provider prepares the workspace, which in one embodiment may be in accordance with steps (**1501,1502,1503,1504**) of panel (**1301**) in FIG. **15**. For example, this may include donning non-sterile gloves, as shown at step (**1501**) of FIG. **15**. This may further include picking up the underbuttocks drape, included with the tray (**100**), by the edge without contaminating the contents and placing the shiny side down under the area of the patient to be prepped as shown at step (**1503**) of FIG. **15**. This may further include using the hand sanitizer as shown at step (**1504**) of FIG. **15**.

At step **2105**, the health care services provider prepares the catheter, which in one embodiment may be in accordance with steps (**1506,1507,1508,1509**) of panel (**1301**) as described in FIG. **15**. For example, this can include donning sterile gloves as shown at step (**1506**) of FIG. **15**. This may include placing a fenestrated drape, included with the tray (**100**), with the shiny side down on the patient without contaminating the sterile gloves, as shown at step (**1507**) of FIG. **15**. This may include filling a test balloon of the catheter assembly with water as shown at step (**1508**) of FIG. **15**, and injecting lubricating jelly from a syringe into the first compartment of the tray (**100**) as shown at step **1509** of FIG. **15**.

At step **2106**, the health care services provider inserts the catheter. In one embodiment, this can be in accordance with steps (**1601,1602,1603,1604**) of panel (**1302**) as described in FIG. **16**. At step **2107**, the health care provider secures the drain bag to the catheter assembly, which can be in accordance with steps (**1605,1606,1607**) described with respect to FIG. **16**.

At step **2108**, the health care services provider detaches the patient portion (**1202**) of the printed instructions (**1001**) from the health care services portion (**1201**). In one embodiment, this occurs by tearing the patient portion (**1202**) from the health care services portion (**1201**) along the perforation (**1203**), thereby transforming the printed instructions (**1001**) or instruction manual from a singular or unitary object into a two-piece object consisting of the patient portion (**1202**) and the health care services portion (**1201**). As described, above, the health care services provider may then discuss the patient portion (**1202**) with the patient and further give the patient portion (**1202**) to the patient to take home after the procedure.

Turning now to FIGS. **31, 32**, and **33**, illustrated therein is one embodiment of a method of using the packaged

US 11,661,220 B2

27

catheter assembly 2901 of FIG. 29. At FIG. 31, a health care services provider 3101 opens the outer bag 2902 that is disposed about the tray 100 and removes the bag 2902 to reveal the packaged catheter assembly 2901 therein. The health care services provider 3101 can then access the instruction manual 1001 that is disposed atop the packaged catheter assembly 2901 in this illustrative embodiment.

The health care services provider 3101 can then unfold the one or more layers of wrap material 2200. Where an additional layer of wrap material 2701 is included, this unfolding step reveals and makes accessible the additional layer of wrap material 2701. Note that portions of the additional layer of wrap material 2701 may be visible, as shown in FIG. 29, prior to the steps of unfolding.

As noted above, in one embodiment the one or more layers of wrap material 2200 can be unfolded to form a sterile field. Turning now to FIG. 32, illustrated therein is a step of the method that utilizes this sterile field. Specifically, in FIG. 32 the health care services provider 3101 places the one or more layers of wrap material 2200 beneath the patient 3201, thereby transforming the area beneath the patient from a non-sterile field to a sterile field. Said differently, by placing the patient 3201 atop the one or more layers of wrap material 2200, the patient is effectively moved from a location that may have not been a sterile field to the sterile field atop the one or more layers of wrap material 2200.

Turning now to FIG. 33, illustrated therein is a step of the method that may be used when an additional layer of wrap material 2701 is included with the packaged catheter assembly 2901. In FIG. 33, the health care services provider 3101 is placing the additional layer of wrap material 2701 atop the patient 3201. Note that in the illustrative embodiment of FIG. 33, the additional layer of wrap material 2701 is fenestrated, in that it includes a perforated opening 3301 suitable for performing a catheterization procedure.

In the foregoing specification, specific embodiments of the present invention have been described. However, one of ordinary skill in the art appreciates that various modifications and changes can be made without departing from the scope of the present invention as set forth in the claims below. Thus, while preferred embodiments of the invention have been illustrated and described, it is clear that the invention is not so limited. Numerous modifications, changes, variations, substitutions, and equivalents will occur to those skilled in the art without departing from the spirit and scope of the present invention as defined by the following claims. Accordingly, the specification and figures are to be regarded in an illustrative rather than a restrictive sense, and all such modifications are intended to be included within the scope of present invention. The benefits, advantages, solutions to problems, and any element(s) that may cause any benefit, advantage, or solution to occur or become more pronounced are not to be construed as a critical, required, or essential features or elements of any or all the claims.

What is claimed is:

1. A medical procedure kit, comprising:

a single layer tray having a first compartment for receiving one or more syringes and a second compartment for receiving a medical assembly, the second compartment bounded by a surface defining an opening allowing access to the second compartment from a top of the single layer tray;

a first syringe and a second syringe disposed within the single layer tray in accordance with an order with which the first syringe and the second syringe are removed from the single layer tray during a catheterization procedure;

28

at least a portion of the medical assembly disposed within the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter; and
an outer packaging disposed about the single layer tray; wherein:

one of the first syringe or the second syringe contains lubricating jelly;

another of the first syringe or the second syringe contains water; and

the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe.

2. The medical procedure kit of claim 1, wherein the single layer tray defines a lubricating jelly application chamber and the first syringe contains the lubricating jelly and is situated in the lubricating jelly application chamber.

3. The medical procedure kit of claim 2, wherein the second syringe contains the water.

4. The medical procedure kit of claim 3, wherein the second syringe is attachable to the Foley catheter.

5. The medical procedure kit of claim 3, wherein the first compartment is adjacent to, and separated by a wall from, the second compartment.

6. The medical procedure kit of claim 5, wherein the lubricating jelly is configured to lubricate at least a portion of the medical assembly when the lubricating jelly is dispensed into the single layer tray and the portion of the medical assembly is passed into the lubricating jelly.

7. The medical procedure kit of claim 1, wherein the first syringe, the second syringe, and the medical assembly are arranged within the single layer tray in a left-to-right usage configuration.

8. A medical procedure kit, comprising

a single layer tray comprising a first compartment defining a lubricating jelly application chamber and a second compartment separated from the first compartment by a wall;

a container of lubricating jelly disposed within the single layer tray;

a coiled tubing coupled between a fluid drain bag and a Foley catheter;

at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the single layer tray and the at least one layer of wrap material;

wherein:

the coiled tubing, the fluid drain bag, and the Foley catheter are disposed within the medical procedure kit; and

the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly.

9. The medical procedure kit of claim 8, wherein the lubricating jelly application chamber is configured to apply the lubricating jelly to the portion of the Foley catheter when the portion of the Foley catheter is passed into the lubricating jelly application chamber.

10. The medical procedure kit of claim 9, further comprising one or more swabsticks disposed within the single layer tray.

11. The medical procedure kit of claim 9, further comprising a container of water.

US 11,661,220 B2

29

12. The medical procedure kit of claim 11, wherein the container of water and the container of water are arranged in accordance with an order with which they are drawn out of the single layer tray.

13. The medical procedure kit of claim 11, wherein the second compartment is adjacent to the lubricating jelly application chamber.

14. The medical procedure kit of claim 11, wherein the container of water comprises a syringe of water.

15. The medical procedure kit of claim 8, wherein the container of lubricating jelly comprises a syringe of lubricating jelly.

16. A medical procedure kit, comprising:

a single layer tray having a first compartment, a second compartment, and a third compartment, the first compartment being separated from the second compartment by a wall;

a first syringe and a second syringe disposed within the single layer tray;

a Foley catheter coupled to a fluid drain bag via a coiled tubing, the Foley catheter disposed within the second compartment of the single layer tray; and

one or more swabsticks disposed within the third compartment;

wherein:

a compartment of the single layer tray defines a lubricating jelly application chamber configured to lubricate at least a portion of the Foley catheter;

one or more of the Foley catheter or the coiled tubing can be passed into the lubricating jelly application chamber to lubricate the portion of the Foley catheter; and

the second syringe is attachable to the Foley catheter during a Foley catheterization procedure.

30

17. The medical procedure kit of claim 16, wherein the first syringe and the second syringe are arranged in accordance with an order with which they are removed from the single layer tray.

18. The medical procedure kit of claim 17, the one or more swab sticks comprising a plurality of swab sticks.

19. The medical procedure kit of claim 16, wherein the first compartment and the second compartment are adjacent.

20. The medical procedure kit of claim 19, further comprising a wall separating the first compartment from the second compartment.

21. The medical procedure kit of claim 20, the first compartment comprising one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.

22. A Foley catheter kit, comprising:

a surface defining a single layer tray comprising at least two compartments at least partially separated by a barrier, the at least two compartments being open via a top opening of the single layer tray;

a first syringe disposed in a first compartment of the at least two compartments;

a second syringe disposed within the single layer tray;

a Foley catheter coupled to a coiled tubing and a fluid drain bag, with the Foley catheter being disposed within a second compartment of the at least two compartments;

the first compartment defining a lubricating jelly application chamber configured to lubricate at least a portion of the Foley catheter when the portion of the Foley catheter is passed into the lubricating jelly application chamber;

one or more swabsticks disposed in a third compartment defined by the surface of the single layer tray; and

a wrap folded about the single layer tray.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,661,220 B2
APPLICATION NO. : 16/944667
DATED : May 30, 2023
INVENTOR(S) : Tomes et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 29, In Claim 12, at Line 2, replace “container of water and the container of water” with
-- container of water and the container of lubricating jelly --.

Signed and Sealed this
Eighteenth Day of July, 2023

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office